

H.R. 2715: THE PAPERWORK ELIMINATION ACT

Y 4. SM 1: 104-68

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HEARING

BEFORE THE

SUBCOMMITTEE ON GOVERNMENT PROGRAMS
OF THE

COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

SECOND SESSION

WASHINGTON, DC, MARCH 27, 1996

Printed for the use of the Committee on Small Business

Serial No. 104-68

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U.S. GOVERNMENT PRINTING OFFICE

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H.R. 2715: THE PAPERWORK ELIMINATION ACT

WEDNESDAY, MARCH 27, 1996

House of Representatives, SUBCOMMITTEE ON GOVERNMENT PROGRAMS, COMMITTEE ON SMALL BUSINESS, Washington, DC.

The Subcommittee met, pursuant to notice, at 2 p.m., in room 2359, Rayburn House Office Building, Hon. Peter G. Torkildsen (Chairman of the Subcommittee) presiding.

Chairman TORKILDSEN. Good afternoon. I welcome all of our witnesses today. I know you had to brave all sorts of unexpected delays in getting here. I appreciate that you have arrived.

Today's hearing is on H.R. 2715, the Paperwork Elimination Act, which I introduced in the first session of this Congress, and in addition to hearing testimony on that piece of legislation, to hear from the small business community and Government representa-

tives on general compliance issues.

The purpose of the Paperwork Elimination Act is to minimize the burden of Federal paperwork demands on small business, educational, and nonprofit institutions, as well as Federal contractors, State and local governments and other persons through the use of alternative information technologies. These would include, but not be limited to, the use of electronic submission, disclosure, or maintenance of information to substitute for paper.

In addition, this act more effectively enables Federal agencies to achieve the purposes expressed in Chapter 35 of Title 44, Section 3501, which is otherwise known as the "Paperwork Elimination

Act."

Specifically, my legislation clarifies provisions on the law requiring agencies to utilize information technology when appropriate, thus allowing individuals with computers and modems the right to use them when complying with Government requirements for submission of information.

This legislation is not mandatory on a business or State or local government entity; it is optional. However, we believe that the intent of this will allow many businesses and individuals to more cost-effectively comply with Federal requirements for information.

Again, I would welcome our guests and look forward to hearing their comments. I will briefly mention who our witnesses are and

then hear testimony.

Dr. Melvin Gerald is the founder President and CEO of a family practice group with six office sites in the Greater Washington area. He is currently Chairman of the Department of Family Practice and Prince George's Hospital, and President Elect of the Medical/Dental staff at Howard University.

Marvin Beriss is the Owner and President of MB Associates, Inc., a systems consultant and value-added reseller specializing in systems using electronic forms integrated with electronic mail and messaging.

Pedro Alfonso is President and CEO of Dynamic Concepts, Inc., a hi-tech firm based in Washington, DC. Sally Katzen is the Administrator of the Office of Information and Regulatory Affairs at

the Office of Management and Budget.

Jere Glover is no stranger to this Subcommittee and is Chief Counsel for the Office of Advocacy at the SBA. Monika Harrison is the Associate Administrator of Business Initiatives at the SBA.

We welcome you all today. The reason that we have asked all of you to sit on the same panel is, once your testimony is concluded, to have a chance for any exchange or any differences of ideas to surface. That way members of the Subcommittee can have a better understanding of any disagreements that may come up or, indeed in that rare case when everyone agrees on the same point, to make sure that we understand that as well.

For time reasons, Ms. Katzen has a commitment that does require her to leave at a certain time. We will ask her to begin with her testimony and then proceed through the panel.

Ms. Katzen?

[Chairman Torkildsen's statement may be found in the appendix.]

TESTIMONY OF SALLY KATZEN, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Ms. KATZEN. Thank you very much, Mr. Chairman. It is a pleasure to be here to discuss H.R. 2715, the Paperwork Elimination Act of 1995. The thrust of this bill, as you said, is to encourage agencies to use electronic submission, maintenance, or disclosure of information to substitute for paper in order to reduce burdens on small business and other members of the public. This is a goal that we share.

Let there be no doubt that this administration is strongly in support of reducing burden on respondents with respect to Government information requests. Where we differ, if at all, is on the necessity of further legislation at this time. I would like to stress "at this time."

In my written statement, I note that the increasing availability of and access to data networks, including the Internet, coupled with commercially accepted standards such as electronic data interchange, EDI, and the increasing level of technology available to the public are coming together to make electronic filing and similar applications a reality.

This is very exciting. It offers enormous potential. However, these technologies are neither magic nor free. Their use requires careful planning and development often at significant expense, and they need to be tailored carefully to provide the benefits of burden reduction to the public without at the same time imposing unrea-

sonable costs and technological burdens on those that they are intending to assist or on the agencies.

I describe in my written testimony the legal and policy framework that is already in place regarding the use of technology gen-

erally and for addressing burden reduction specifically.

"OMB Circular A130" emphasizes that modern technology can be used to help the Government and the public in the Government's collection of information. It cautions, however, that information technology is most useful when, among other things, the respondent population has access to the necessary information technology. It specifically directs agencies not to convert to electronic filing if that in itself would impose substantial costs on the public, especially small businesses.

We were very happy that these policy concerns were codified in the Paperwork Reduction Act of 1995, which passed this house without a single dissenting vote. When the President signed the bill, he specifically recognized the concerns that you yourself have

addressed, namely he said:

"From this point forward, I want all of our agencies to provide for the electronic submission of every new Government form or demonstrate to OMB why it cannot be done that way. The old way will still be available, but I think once people see how fast and efficient electronic filing can be we will see less paperwork and more of these".

"We are trying to do our part," he said, "in good faith, the way Members of Congress intended the executive branch to act."

It is in that spirit that we have carried forth his objectives.

Similar optimism for the use of information technology for improving Government programs was reflected in the recently enacted Information Technology Management Reform Act of 1996, which was attached to the DOD reauthorization statute. It adds an important dimension, and that is, to instruct agencies to reengineer their work processes before they make an investment in information technology. In other words, do not automate the mess. Do not just put a computer at the front of the process. Think about what it is you are doing, why you are doing it, how you are doing it, and then ask, can information technology help you get there better.

Most of my testimony talks about some of the instances of Agency use of information technology. I will not elaborate on those now. I would be happy to respond to any question about them, if you

would like.

The point I would like to make is that given the increasing responsiveness of agencies to the various initiatives that have been in place, the fact that the Paperwork Reduction Act took effect just last October, and the Information Technology Management Reform Act will not be taking effect until this August, we question the timing of this particular legislative effort. The law and its implementing guidelines have gone through several cycles recently.

I, as the Administrator of the Office of Information and Regulatory Affairs, have been literally churning out guidance to agencies so that they will be able to follow through on these initiatives. I would suggest, therefore, that it may be appropriate to take a

breather and let the agencies begin to catch up.

The only other point that I would like to make now is, as you so clearly recognized in your opening statement, any requirement has to be optional for small businesses and other entities, because they may not have the technical or financial capability to come online and, therefore, may need to have the paper route available for them. So, too, some of the agencies are not up to speed. Some of them are saddled with quite obsolete equipment, and some of them do not have the necessary infrastructure. To mandate them to make this available electronically, may force them to make investment decisions before they really know what they are doing.

Pushing agencies to move too quickly would be contrary to the most recent statute which says don't automate the mess; instead, figure out what it is you want to do first. Given the current budgetary constraints, I am not particular sanguine that all of the agencies will be able to get up to speed as quickly as I, for one, would

like to see, or, I assume, as quickly as you would like to see.

I think that encouragement and stimulus is appropriate, but we have to keep reality in mind and remember that some of the agen-

cies simply do not have the technical capability at this time.

I want to underscore that we are impressed with your interest in the area. We believe that legislation or hearings such as this provide an important stimulus to the agencies. We want to work with you to figure out how best to bring the agencies toward the objective that we share.

Again, I thank you for the opportunity to begin this dialogue

with you.

[Ms. Katzen's statement may be found in the appendix.]

Mr. TORKILDSEN. I will take a moment from our regular order of witnesses and would ask if the Ranking Member of the Subcommittee, Mr. Poshard has any opening statement he would like to make?

Mr. Poshard. Mr. Chairman, thank you. I apologize for having arrived late. It is always 15 different things going on around here at the same time. Let me just in the interest of time ask you unanimous consent to submit an opening statement for the record.

Chairman TORKILDSEN. Without objection, so ordered.

Mr. Poshard. Thank you.

Chairman TORKILDSEN. I would ask all of the witnesses to take a hint from the very distinguished congressman from Illinois. Brevity is always appreciated. You do not have to be quite that brief.

I failed to mention at the beginning of the hearing that all of your written statements will be included in their entirety in the record. If you could, please summarize. As Ms. Katzen did, observe the 5-minute rule that we have. We would appreciate that, and that will allow time for questions at the end.

Mr. POSHARD. Mr. Chairman, if I may say, I just got a call from the Rules Committee that I have to get over there, so I will be back

as soon as I can.

Chairman TORKILDSEN. Your presence has added enormously to our hearing, Mr. Poshard. Thank you.

[Mr. Poshard's statement may be found in the appendix.]

TESTIMONY OF MELVIN GERALD, M.C., TESTIFYING ON BEHALF OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS, PRINCE GEORGE'S COUNTY, MARYLAND

Dr. GERALD. I am Melvin Gerald, a practicing family physician in Washington, DC. Currently I serve as a member of the Commission on Health Care Services of the American Academy of Family Physicians. The academy is the medical specialty organization representing over 80,000 practicing physicians, family practice residents, and medical students with an interest in the specialty of family practice.

I am pleased to appear before you this afternoon on behalf of the academy to discuss means to reduce the Federal paperwork burden imposed on practicing family doctors and other small business enti-

ties.

Although the public generally does not equate a physician's practice with a "small business," the practice really is a business. Almost half of the academy's practicing physician members are in

solo practice or in a two-person partnership practice.

We physicians are small employers similar to other small employers in fields other than medicine. We are appropriately subjected to the same documentation and reporting requirements as other business entities. We must comply with the same employment regulations issued by the Department of Labor, conduct the same worksite safety programs required by OSHA, observe the same disposal rules promulgated by EPA, and perform the same quarterly rituals required by IRS. And we must record, submit, store, and keep evidence of our compliance.

Health care is both a service and an information industry and is becoming more information-driven every day. Every action a physician takes on behalf of his patient from the first moment of their

first encounter has an information component to it.

Every action must be recorded documented, attested, filed, submitted, justified, resubmitted, and stored in accordance with an incomprehensible tangle of standards, regulations, and third-party

requirements. Medicine has become a paper chase.

Unfortunately, all of this paper chasing does not help patients receive better care or protect them from harm or lower the cost of health care. Rather, it takes away from the time that we have to care for patients. A recent academy survey found that family physicians spend on an average 20 percent of a 60-hour work week on administrative tasks.

Each new administrative requirement measurably increases the cost of providing health care services and diverts resources from direct patient care. In my experience, an unreasonable percentage of those administrative tasks are the direct results of Federal regula-

tions and the attendant documentation requirements.

Over the years, the layers of Federal regulations and their attendant paperwork burden have had a profound effect on the practice of family medicine. Medicare, which typically covers as many as 40 percent of a family physician's patients, is one of the most complex laws in the land with literally thousands of pages of regulations, instructions, directives, and forms.

The Physician Payment Review Commission noted in its 1994 report to Congress that increased paperwork was the second most

frequent complaint registered by physicians with respect to the Medicare fee schedule.

A 1993 study found that over 90 percent of practicing family physicians, regard regulation by Government Agencies and the amount of paperwork involved in complying to be a most significant chal-

lenge for their practices.

As you might expect, the acuity of bad feeling about Governmentsponsored paperwork goes up as the size of the physician's practice goes down. We commend the House Committee on Small Business and Chairwoman Meyers for their tireless efforts to reauthorize the Paperwork Reduction Act. We are especially grateful for the opportunity to comment today on the Paperwork Elimination Act of 1996, sponsored by Representative Torkildsen.

The Paperwork Elimination Act would further reduce the work demands by the Federal Government by advancing the use of alternative information technologies to satisfy Agency information col-

lection requests.

It would require the director of OMB to promote the use of electronic submissions, maintenance, and disclosure of information as an option for entities complying with Federal regulations, and would require individual agencies to make this option available to those of us who are on the receiving end of the information requirements.

Appended to my written testimony today are examples of the kind of information, collection, and recordkeeping that the Federal Government imposes on practicing physicians. At first blush, it may not seem that the issues raised therein are amenable to redress through alternative forms of information technology.

However, I want to assure you, I want to assure the Subcommittee, that the steps you are taking to require Federal agencies to accept electronically submitted information will ultimately have a profound and very positive impact on a physician's ability to satisfy

these mandates.

Our health care system is changing and evolving rapidly. It is spinning off new delivery system configurations, as payers and providers who once functioned relatively independently are now merged into HMO's, provider networks, and consortia.

At the heart of the movement toward greater integration, what makes it all possible is the emergence of shared information systems that allow us to track cost, quality, and outcomes. Ultimately, it is information demanded at many different levels, for many different market players that is driving the innovation in health care.

I see my time is running out, so I will not read the rest of my prepared statement, but I would like to say this. Filling out forms and providing information to different regulatory authorities, to different health plans, to different federally sponsored organizations

such as OSHA and others, consumes a lot of our time.

We, in a small practice like ours, hire people specifically just to fill out this information. If there were some standard where the information could be entered on a disk and submitted electronically, this would reduce our work and measurably increase the amount of time we are able to devote to direct patient care. We are in support of your action here today.

Chairman TORKILDSEN. Thank you very much, Dr. Gerald. Like Ms. Katzen, you have brought up many interesting points, but I will wait until all the witnesses have testified before going into questions.

Mr. Beriss?

[Dr. Gerald's statement may be found in the appendix.]

TESTIMONY OF MARVIN BERISS, PRESIDENT, MB ASSOCIATES, INC., FAIRFAX, VIRGINIA

Mr. BERISS. Thank you. I guess I am happy to be here. My company is a small business, is the first thing I want to say, and what we focus on is electronic forms and electronic, as you said, with electronic mail messaging. Our focus is narrow, and it is to help business and Government increase productivity, and doctors increase productivity using electronic forms.

We will be happy to help anybody that wants to get on board with this Paperwork Elimination Act, which we think is a great idea. I brought along some statistics that I got from JetForm Corporation, which is a company that specializes as well in electronic forms. I think they might be worth reading. You may already know

them; I do not know.

As a Government, we require more than 7,000 forms or reports from the public. The public sends back more than 9 billion responses. After excluding tax forms, that number reduces to 7 billion. The public spends more than 1 billion hours responding to Government forms. These forms are applications for variance, benefits, services, compliance information, licensing, permits, and so forth.

The Government has to get the forms to the public along with instructions on how to use them. Then the public fills them out and returns them. When the responses come back, the Government makes sure they were filled out correctly. Finally, the forms are

processed as part of a larger process.

Now, for many citizens, forms are the primary they interact with Government. For these kinds of applications, the potential that intelligent, electronic forms and the Internet holds to improve service

and at the same time lower cost is enormous.

How big is "enormous"? The estimate, at least by JetForm, is \$22 billion. The \$22 billion is for mailing, receiving, rekeying, and routing of the paperwork. I think there are a lot of savings that can

be achieved with electronic forms.

I will not get into all the details, but I have listed in my written testimony all of the benefits electronic forms bring and their low cost and ease of use. Given the commodity nature of personal computers, telecommunications, and the Internet, the cost of getting into these things is very, very low. By the way, it is building a very big industry.

My final sales pitch, my office is in Northern Virginia. As you may know, Northern Virginia carries about half the Internet traffic in the world today. We have a lot of companies that are specializ-

ing in this area, electronic forms, and the Internet.

JetForm itself, for example, just relocated from Waltham, Massachusetts, to Falls Church. We are ready to help in this area, for anybody that would need it. All we can say is we support what you are doing.

Chairman TORKILDSEN. Thank you, Mr. Beriss.

Mr. Alfonso?

[Mr. Beriss' statement may be found in the appendix.]

TESTIMONY OF PEDRO ALFONSO, PRESIDENT, DYNAMIC CON-CEPTS, INC., WASHINGTON, DC, TESTIFYING ON BEHALF OF NATIONAL SMALL BUSINESS UNITED

Mr. Alfonso. Thank you, Mr. Chairman.

My name is Pedro Alfonso. I am President of Dynamic Concepts, Inc., a small business based in Washington, DC. I am an Active Member of the National Small Business United, where I serve on the Board of Trustees and am chair of the Procurement Committee. I was also a delegate to the 1995 White House Conference on Small Business.

I very much appreciate this opportunity to represent the needs of the Nation's small business community and to comment on your very pro small business bill. National Small Business United represents over 65,000 small businesses in over 50 States.

Our association worked with elected administrative officials in Washington to improve the economic climate for small businesses growth and expansion. We have always worked on a bipartisan and

proactive basis.

In addition to the individual small business owners, the membership of our association includes local, State, and regional small business associations across the country from the smallest Small Business Associations of New England to the California Small Business Association, which is quite large.

NSBU was one of the original supporters of the Paperwork Reduction Act, and was greatly encouraged by its strengthening last year. The role that the Small Business Committee played in that

strengthening was significant and very much appreciated.
Chairman Torkildsen, you have not covered an area in the law that can be expanded and improved. Your bill provided an excellent addition to the underlying act. I have been asked to be here in order to provide comments on H.R. 2715, the Paperwork Elimi-

nation Act, sponsored by yourself.

I believe that this bill could significantly improve and streamline the Federal paperwork morass in which too many small businesses find themselves. I believe this is the case not simply because small businesses will be able to meet Federal paperwork requests electronically, but because this requirement will force Federal agencies

to enter the late 20th Century in terms of technology.

This technological advancement will open new doors for not just the retrieval of information, but also its storage and dissemination. Ideally, agencies will be able to eliminate significant chunks of redundant information. Where regular reporting is required, it will be easy for small businesses simply to report on what is new or changed, rather than refiling all the information on a regular basis.

Just 3 weeks ago at a hearing hosted by the full committee on EPA regulations, I understand that there was a demonstration of a new project co-sponsored by the Printing Industries of America

and the Environmental Defense Fund. The project included com-

puter software that made filing of EPA data quick and easy.

Following this model, the small business owner would use a supplied software on his own computer. Once completed that data could be immediately sent by modem to the Agency. With all that information automatically stored, only relatively quick updates would be required in the future. Moreover, the software would help with overall regulatory compliance.

When data is entered, a program could automatically determine what level of compliance is required of that party. That software and system is in place now. Fundamentally, this move appears to be both a win/win for regulators and the regulated. Everyone's lives

would be made significantly easier.

Of course, agencies may choose less sophisticated ways to electronically submit data to the Federal Government. Largely because of design and distribution of sophisticated software for paperwork and regulatory compliance, the kind that will really help will be time-consuming and expensive. H.R. 2715 does not appropriate any money.

However, I believe that the significant savings that could be realized in terms of reduced Federal personnel, not to mention enor-

mous private sector costs, could certainly offset those costs.

Nevertheless, there is a good chance that many agencies could take the quick and dirty route to compliance with H.R. 2715 and allow electronic data submission, but not make it user friendly.

While this scenario certainly leaves us no worse off than currently, it must be recognized that only a very small subset of the small business community use a system that is not designed with their needs in mind.

While H.R. 2715 appropriately vests the Office of Management and Budget with management and oversight to prevent these problems, I also think that it is important for Committees such as this one to hold vigorous and pointed oversight hearings. Congressional pressure can produce remarkable results along these lines.

Of course, we also have the opposite concern that agencies would shift so thoroughly to electronic data that small companies without

a technology base would be left behind or unserved.

While on the whole the small business community is technologically advanced, and in some sense more so than their larger counterparts, one in five small businesses still do not own a com-

puter.

While this problem is not a good reason to slow progress of H.R. 2715, it is something to bear in mind, especially in terms of future oversight hearings. This legislation appears to be a very major step forward for relieving the small business paperwork burden; though, I stress again that implementation over the next few years would be paramount.

Thank you for your inviting me to testify, and I look forward to

taking any questions that you may have on this bill.

Chairman TORKILDSEN. Thank you, Mr. Alfonso.

Mr. Glover?

[Mr. Alfonso's statement may be found in the appendix.]

TESTIMONY OF JERE GLOVER, CHIEF COUNSEL, U.S. SMALL BUSINESS ADMINISTRATION'S OFFICE OF ADVOCACY

Mr. GLOVER. Thank you, Mr. Chairman. With me today is Ray

Marchakitus and Jim O'Connor from the Office of Advocacy.

The 1995 White House Conference was the first White House Conference to significantly use electronic data. One of the things that we found from that conference is that, one, the White House Conference delegates learned very quickly to use that as a way to exchange information and for us to provide information to them.

In addition, they looked at the whole electronic information age and came up with several recommendations, one of which is the basis for your proposed legislation today. Now, these recommendations are things that we use as guideposts and directions for what

small business' goals were.

Let me just say that based on my experience in business, that there are many small businesses, some of which were businesses that I helped create, which are closer to the Stone Age than they are to the Information Age. For those businesses, the idea of being forced to provide information in a specific format is something they would oppose very violently.

It is fortunate this bill is very clear that that is not what we are talking about. I think that is important because we want small businesses to go at their own pace, but we also do not want to have such barriers that would raise the cost to entering and operating

small businesses.

Clearly, forcing firms to automate before it was appropriate for that particular firm to do so, would cause real problems. The Office of Advocacy itself is being pulled slowly but surely into the Information Age, as is SBA. At SBA, for example, many of our district offices had 286 computers and were not on the Internet.

We are just now bringing those onto the Internet, and they are beginning to be able to function very effectively that way. Those are changes which have occurred fairly recently. The Office of Advocacy is now publishing and releasing most of its studies and in-

formation on the Internet.

When we complete those, our banking study which is about 400 pages long, we will be able to publish that for all States on the Internet, making it very easily available to people around the coun-

try.

Likewise, other studies that we have done, we recently published our "Procurement Opportunities," which is a guide to the new procurement legislation, and we published that on the Internet simultaneously with our releasing it. That is certainly progress. I lay this out in the testimony of agencies' activities.

I think the President and the Vice-President have directed that this be a priority, and you have seen a lot of movement by the agencies in that direction. I think that is important. One of the

things I would mention is the U.S. Business Advisor.

In less than a year, what we have seen, much like the Congress, the ability to make vast amounts of information available throughout the country and available quickly and easily. Small businesses, through the U.S. Business Adviser, can tap onto a variety of information.

One of the things we look at this time of the year, which is tax filing time, I was very pleased to double-check and quickly see that there was a form for an extension of time available for us quickly and easily on the Internet, so we did not have to scurry around April 14 looking for someone who had a copy of that form so we could submit that. Those things are happening and happening very quickly.

I think the availability of low-cost computers, the availability of Internet information, all of those are growing very rapidly. The learning curve both in the Government and in the private sector is increasing dramatically. Things that we would absolutely not even think about doing either as business or Government officials, are now done instantaneously without really spending much time.

Those things are changing dramatically concerning the improvements and changes that you are suggesting. I think there is no question those things should happen. The only question is when they should happen. I think with that I will be happy to answer any questions.

[Mr. Glover's statement may be found in the appendix.]

TESTIMONY OF MONIKA HARRISON, ASSOCIATE ADMINISTRATOR, OFFICE OF BUSINESS INITIATIVES, U.S. SMALL BUSINESS ADMINISTRATION

Ms. HARRISON. I appreciate this opportunity to testify before you today, specifically, to inform you about the outreach and training activities conducted by the U.S. Small Business Administration on electronic commerce and electronic data interchange.

As you pointed out, I provided a longer statement to the Sub-

As you pointed out, I provided a longer statement to the Subcommittee and have also provided a set of materials which we have developed over the last 18 months for outreach and training efforts. You will see various definitions of electronic commerce and electronic data interchange, so I will not read those today.

We have spent the last 18 months trying to inform the small business community about the Federal Government's change from a paper-based procurement system to a paperless procurement system.

We have actually been involved in formal outreach and training activity since September 1993, when we originally proposed to the Department of Defense that we, through our own resources and our networks, could assist them in meeting their outreach and training objectives. All of our outreach and training activity has been focused on three particular objectives: To inform, to educate, and to train the small business community.

These three discrete objectives recognize the differences in the many types of small businesses which we serve and which would be interested in knowing more about the Government's transition

through the use of EDI in procuring goods and services.

A significant part of the SBA's outreach and training activities were conducted under the terms of the interagency agreement between the SBA and the Department of Defense. That agreement was signed in September 1994. It took a while for their resources to be ready, and on April 10 through 19 and on April 7, 1995, we ended up jointly training 542 personnel in "train-the-trainer" sessions.

The purpose of "train-the-trainers" was to prepare trainers who could then go back to their local communities and on an ongoing basis train those small businesses who had an interest and a need to know about electronic commerce and electronic data interchange.

The 542 personnel included SBA personnel, representatives from the Small Business Development Centers, representatives from the Women's Demonstration Sites, representatives from other Federal agencies, and other representatives from defense-affiliated organizations.

Since the time that "train-the-trainers" activity took place and December 1995, those trainers have now informed, educated, or trained over 11,000 small business throughout the United States. In addition to this "train-the-trainer's" activity, we have con-

ducted a national series of co-sponsored training events directly for the small business community. From the period of April 11, 1995, through March 19, 1996, we have had 21 co-sponsored training events, and a total of 3,188 small businesses have attended these

We have entitled this training "EDI: Your Link to Profits," so that it would be attractive to the small business community and is designed to be an overview of the Federal Government's EC/EDI

Program.

In addition to our training activities, SBA has also created an extensive library of information about EC/EDI on SBA Online, our electronic bulletin board for small businesses and also on the SBA

home page.

Last year, approximately 500,000 calls were made to SBA Online. In addition, approximately 18,000 hits on the home page are being logged weekly. We know that many of these hits involve a search for information about electronic commerce, electronic data

interchange.

Among the many types of information available through these electronic resources are fact sheets on a variety of EC/EDI topics. They can find out about public and private sources of training by geographic area. They can view the most frequently asked question and get the answers to those questions. They can get the names, addresses, and telephone numbers of all of the certified valueadded networks. I have just given you three examples of the types of information and training that the SBA has conducted and continues to conduct and which we believe has provided a valuable service to the small business community. I will be happy to share other examples with you during this hearing and look forward to answering your questions.

[Ms. Harrison's statement may be found in the appendix.]

Chairman TORKILDSEN. Now, before I ask a few questions, I would just like to ask any of the witnesses, was there any statement that anyone made that you either disagreed with or feel strong enough to say that you agree with it? I mean, would anyone like to comment on anything that has been said so far?

[No response.]

Chairman TORKILDSEN. What a great panel of witnesses we have. To start off, a few questions. All of the witnesses, each of you, have brought up relevant points. From Ms. Katzen, I will start off with a statement that you had. You said that OMB had asked the different departments to "Think about what it is you are doing."

Now I think it is something that all Americans hope that it is not the first time that it has been asked of the Federal Government. Although, given bureaucracies and the way they respond, it is a question that has to be asked.

My question for you is, How long is this examination process going to go on in the administration? The concern that you have, Is this like in the Department of Defense where President Clinton ordered a "Bottoms-Up Review" and had his results in less than a year, or is this a longer-term proposal? This examination that OMB has asked departments to do, is it structured or is it open-ended?

Could you give us a little more detail on that?

Mr. KATZEN. There are actually two different strains to that. The first is a general reexamination of what agencies do, which is part of Vice-President Gore's reinvention efforts. That has had two phases—the first took place in the first year, and the second took place in the second year-looking at different functions that the Government performs and asking whether those are functions that should be performed by the Government; and if so, at what level of Government. Are they properly handled with the Federal/national level, or are they better handled at the State and local level? Whether there are ways in which the private sector can or should participate? We have already seen a large number of reports of the reinvention effort.

The second involves the budgeting process. This is what I was referring to when I used the, "Reengineer your work processes before you automate the mess" phrase, which is based on the Information Technology Management Reform Act that was recently passed. That act, in codified effect OMB Circular A130, which was specifi-

cally directed to investments and information technology.

This is a very exciting time because there is so much information technology that is available. How is it being used? Is it being used

in a way that provides real returns to the American people.

As part of the budget process in OMB, when an Agency comes in with a proposal for a significant investment in information technology, we want it to apply best practices from the private sector, which includes capital budgeting processes, and which starts with questions such as, "Why are we doing this? Is this the right way to do it?"

We ask for that kind of examination with some documentation that they have thought these issues through, that they have a management structure in place, that they perceive that they can actually get from here to there, and other kinds of good business practices. As agencies come forward to revamp their information infrastructure within the Agency or to invest in a new project, we run through those issues.

Chairman TORKILDSEN. I applaud the questions you are asking.

Are you demanding answers in any time certain?

Ms. KATZEN. Yes. In order to proceed with a significant investment, Agencies have to have satisfied OMB that they have answers, not just that they asked the question, but that they have answers, swers that pass, as I said earlier, a reality check. One of the things that the most recent statute has put in place is a variety of different interagency groups that can be used to assist and advise OMB in that effort.

Chairman TORKILDSEN. Just to throw out a question to any of the witnesses. Do any of you know on average how outdated technology is that the Government tends to buy in general? I mean, would any of you like to take a guess at that?

Mr. KATZEN. It is varied. Some of it is extraordinarily outdated. I would be uncomfortable, however, if I were to try to say which of the major departments who are, as Mr. Glover said, closer to the

Stone Age than to the Information Age.

One thing we know is that many Agency components cannot communicate within the Agency itself. At some agencies, you have one set of computers and one LAN that operates within the program office and an entirely different architecture, with an entirely different hardware, and an entirely different software that operates

I know of one assistant secretary who has to log on four times to be able to communicate with those people within her department that she would ordinarily speak to because there are four different

LAN's that she is connected to. I think it is appalling.

As someone who is charged with some responsibility in this area, I have had a number of—I keep coming back to this word—"reality checks," as I talk with some of the agencies. Many of them were placed in this position because of the "peculiarities," if I could call it that, of the procurement laws, which had structured Government procurement in such a way that by the time they actually got product on site it was already obsolete. Then they had absolutely no insenting the desired Whether Procurement in the structure of centive to do it again. What you did was they kept adding to it. They kept building on this obsolete monstrosity until they had something held together with rubber bands and band-aids, but did not really serve us well.

The one comment that I heard as I was listening to the responses to your very first question is the notion that this is going to save a lot of money. I do believe that that is the case. But I want to caution that there are up-front costs. Those may well be very significant for some of these agencies. I know to do the kind of wholesale replacement that is called for in some departments would take an enormous amount of money that we do not see in the budget right

Chairman TORKILDSEN. You do agree that for both the agencies, as well as the private sector, there will be long-term cost savings?

Mr. KATZEN. Yes, sir.

Chairman TORKILDSEN. I appreciate that.

Just on your point about the procurement and the rationale, I mean, the crazy laws the Federal Government has is not limited to the Federal Government and why one official can have four dif-

ferent LAN's that she has to log onto.

The reason the legislation was structured the way it is because I did not want to tell departments that they had to go out and have a LAN system or any type of system. I wanted to get to the end result, which was to allow those businesses, especially small businesses, that are able to do so to meet their reporting requirements electronically.

That way the Agency is not being told, "Well, you have to buy this computer or that you have to invest in this LAN system." It is saying, "Focus at the end result." I will walk you through just my own experience, which is not that of a Federal Agency but of a State Agency.

Briefly, I was commissioner of Labor and Industries in Massachusetts, a very, very small department. It only had five people in it. It had kept a 3-by-5 index card operation going since 1946. Even when I was appointed in 1991, they had not abandoned it a bit.

I found out that, indeed, in the 1970's the then-administration had mandated that the whole department have a computer. Nobody used the computer for the first year and a half because while they had been mandated to buy a computer, no one had mandated them to use it.

One small part of the department used the computer, but none of the other ones did, even though at the time it had more than enough capacity to meet all of these needs. Bureaucracies do not take initiative. They respond to an outside stimulus. In the Federal Government, that is either going to be the President of the United States or the Congress.

Now, we can say, "Well, we would really like you to do this sort of thing, and hope that different departments pretty soon catch on to the idea. However, unless there is a directive from either the President or from the Congress, that "This is what a department has to do," in this case to be user-friendly with computers, I just

do not see it is going to happen.

Mr. KATZEN. Mr. Chairman, as I said in my statement, when the President signed the Paperwork Reduction Act, he announced what was then a new policy. He announced it very clearly: "Agencies will henceforth and forever more when they are presenting an information request to OMB show that it can be answered electronically or demonstrate why not."

We have seen a large number of electronic information requests come in. In fact, given where I thought some of the agencies were, I was pleasantly surprised by how many forms can be answered electronically. We added a question to our paperwork clearance form just last year: "Can this be answered electronically? If not, why are you not doing that?" A number of Agencies said "yes."

The Agencies are beginning to respond to the President's initiative in this regard. We also have taken dramatic steps to change procurement laws with the obvious help of the Congress, which passed two major pieces of legislation, and we are looking now to even further encouragement of modular acquisitions, so that Agencies can be further up to speed with a technology that changes almost even before you can even get the first set of forms filled out.

I do not want in any way to appear the least bit unreceptive to your goals or to the support that you can give us by oversight and by prodding us to do a better job. I applaud this effort, because I think it is essential, not just for the President to speak, but for the Congress to speak, so we can speak in unison on this issue.

As I heard the doctor speak about the amount of paperwork, it was very moving. It is why we tried in health care reform to cap some of those costs. We are still hopeful that we can eliminate

some of those costs.

For every business, for every State and local government, for every entity big and small in this country, there is an enormous burden from the paper-based system that we have that we want to help pare back.

Chairman TORKILDSEN. I want to shift focus, and Ms. Katzen you brought up an important point. I know you have to depart and Dr.

Gerald has to depart as well.

I would like to ask, Dr. Gerald just briefly, while we heard from Mr. Alfonso that one in five small businesses in general are not computerized, in the medical field I would think a much higher percentage, higher than that 80 percent, are computerized. Do you have any figures on that at all?

Dr. GERALD. I do not have.

Chairman TORKILDSEN. Could you speak into the microphone, please?

Dr. GERALD. I am sorry. I do not have exact figures, but we can

get that back to you.

Chairman TORKILDSEN. That would be appreciated. Then just looking at the work, the requirements that you mentioned specifically, OSHA is an enormous paperwork generator.

Dr. GERALD. There are others.

Chairman TORKILDSEN. There are others. The cost savings in the medical field, I think, would be enormous. I think I can guess adequately, and I will wait for the exact numbers, that most medical offices, even the smallest ones, are computerized to some extent now.

The cost savings and the labor savings would be enormous if you had a computer reporting, for example. A Medicaid claim, again, many times you hear stories about, "Well, we forgot to fill in one word and we got the claim rejected," 3 months later that it was not paid. In the meantime, I still have to pay my staff and everything.

By the time they fixed the form, it cost them more to adjust the form a second time than the amount of money we are talking about being reimbursed. A computerized system could eliminate the delays in reimbursement, greatly reduce the cost there. Is that ac-

curate as a benefit?

Dr. GERALD. That is completely accurate not only in that area, but the managed care going the way it is going now and many of the managed care organizations are federally qualified organizations. The amount of paperwork that a provider has to fill out to comply with those organizations is tremendous. You have to fill that same paperwork out every 2 years. In our practice, we have had to hire someone just to do that.

Chairman TORKILDSEN. I appreciate your contributions to this as Ms. Katzen. I understand you have to depart. I would like for the

other witnesses to remain and go over a few other points.

Mr. Glover, you asked the magic question, I believe. You said the question is not whether or not to make this change, the question is when. As I am a firm believer that if you give someone a time certain by which to accomplish it, you will have a much better chance of getting it accomplished than if you give them no time certain at all.

When do you think is reasonable to say all departments have to be able to receive the information they are requesting. I mean, the alternative is if they do not need the information, they should not be requesting it to begin with. When is a good time for you, for different departments within the Federal bureaucracy, to meet this

requirement?

I am not the expert on what each independent Agency is actually doing. I can tell you that, given the significant accomplishments in just the last few years. When I talk to folks who were with SBA in the old days, the "old days" being 3 or 4 years ago when we did not have electronic. We did not even have E-mail. All of those changes have happened in the last 3 years. Where it becomes a priority, we see the agencies respond very quickly.

I think that there may be need to be some flexibility as to the effective date. Clearly, your suggestion that there be a time certain, without it, we recognize that it will slip. We will be having this discussion 2, 3, 4 years from now if something does not happen, if

there is not some additional encouragement.

I think that Ms. Katzen is correct, that the President has taken action. He is moving forward. Oversight, congressional encouragement, direction is also welcomed. It tends to, perhaps, expedite the process as well. I think there are some areas where everybody agrees that it needs to happen, and a little extra nudge is certainly in order.

I cannot tell you whether the effective date ought to be year from now or 2 years from now, for example, but there is certainly perhaps some waiver provision where someone could come into OMB and explain why they could not make the deadline and submit a

copy to the Congress.

If they have a honest, legitimate concern, I am sure we are compassionate and we would understand that. On average, we ought to be able to do this fairly quickly, given the learning curve that we have experienced in the last few years.

Chairman TORKILDSEN. I think those are very reasonable sugges-

tions.

Mr. Alfonso, speaking on behalf of National Small Business United, do you see any other things to be concerned about. The point you brought up is we want to make sure that these agencies are user-friendly. We can do that through oversight. Your line, I will borrow it if you don't mind. "Pressure produces remarkable results."

I wholeheartedly agree on that, and making sure that this is done in a user-friendly manner. Also, agencies do not get to the point where they prohibit those small businesses which are not online yet from meeting their requirements for reports in the old fashioned way. Are there any other concerns you think we need to address in this legislation?

Mr. ALFONSO. Mr. Chairman, certainly. I can elaborate even when I said one in five businesses do not have at least computers. You are including the grocery stores, you are including the five-per-

son janitorial service, and the small printer.

There are a lot of small businesses out there that may not have access, but certainly the majority of those that have reporting requirements, those that must respond to regulations and to the EPA, Department of Labor and to all the other agencies that are

requesting mounds of reports, generally would have some access or

availability of electronic processing.

In addition, I will say that agencies must start somewhere. Certainly, they have many of the procurement regulations with EDI. The Department of Defense has come out with the saying that they will provide many of the requests for small purchases over electronic data interchange and that ready or not, they say here we come. Small businesses had to gear up to make sure that they could respond to that. I believe that it should also be in the same sense that they need to be able to accept reports from small business, those that are capable of doing it, without shutting out those who are not prepared. They certainly are forcing the issue on other occasions that accommodate agencies. I certainly think that your particular bill would allow businesses to be able to respond electronically also.

Chairman TORKILDSEN. OK.

Mr. Beriss, given that you make your living on some of the things we are discussing right now, do you see any pitfalls? I mean, I think the technology is well-advanced, the hardware is reasonably priced. Do you see any pitfalls in just the mechanics of implementing this?

Mr. BERISS. Not at all. In fact, from my perspective, a lot of the concern that has been expressed by small business, I do not share. I think being a small business you are in business to keep your

costs down and increase your profit.

Those people who have new technology can do that better than those people who do not. The people who do not have technology may fall by the wayside. Notwithstanding whatever the Government or anyone else does, competition is going to force them into using the new technology.

Now, the new technology is one of the common concepts these days of a software company or an online service is, "Let us give it away for free." A Compuserve or an America Online, you get 10 hours free, and they send you a disk every Sunday so that you

have enough to get started with.

I do not think that the technology is any kind of an obstacle at all on the part of the small business community. Being somebody that promotes that technology and makes money out of selling it.

I see a lot of people adopting it all the time.

I am less knowledgeable about what Federal agencies would do without the external pressure that you are providing, because there is little competition for Federal agencies. They do not have the same incentive that other companies might have.

Chairman TORKILDSEN. Yes. Federal agencies are still one of the

last monopolies left in a global economy.

Ms. Harrison, with your work with the small business community, any concerns you think we should be aware of or, in general as Mr. Alfonso has stated, clearly anecdotally the people who I have talked to have been all very favorable to this idea. Any concerns that you think we should be aware of that you did not mention in your testimony?

Ms. HARRISON. I would echo the points that were made. The technology is there. I think that for people to assume that small

businesses, by virtue of the size, are unsophisticated or perhaps do

not have access to technology is probably not correct.

You have some people who are sole proprietors who are very highly technologically advanced. They use everything that is out there to help them do their business and to do it efficiently and in the most cost-effective manner.

Part of what we have tried to stress in our training is that, first of all, electronic data interchange, for example, is not a new idea. Although because the Government is now deciding to use it for its

own procurement process, it has been around for a long time.

Mr. Glover points out in his written statement that the automotive industry, retailing, financial services, and others have for many, many years used EDI. While it starts with a large corporation, they have then had all of their small businesses or other suppliers use the same electronic data interchange process.

We have tried to say to small businesses,—and you need to do this for any kind of compliance reporting or friendly exchange of information through data interchange,—it is technology that is un-

derstandable.

I keep saying it is not rocket science, and you do not have to have a Crag supercomputer or a massive staff to do this in your small business. We need to reassure people—that is, small businesses in particular—that this is within their pocketbook and that it helps them do something more efficiently and more effectively.

No matter what we do, no matter how friendly it is perceived at the beginning, there is an education component to helping them understand what that is all about. Second, it will take some time.

There is a financial issue for some small businesses.

A computer may only cost \$3,000. However, by the time they put the whole system together, it may be \$6,000, and maybe they do not have \$6,000. There needs to be a window for them to acquire the technology and become proficient.

Third, While it is always a good idea to take advantage of any technology, there will be some small companies who will feel that

this is yet another impediment for them.

Again, no matter how happy they are that they do not have to fill out forms, their unhappiness is with having to provide the data in the first place. If you make it easier for them to do it electronically, that will make them a little happier, but their concern is that there is still data that must be collected and sent and perhaps accounted for. That cost is not entirely resolved by electronic data transmission, and we probably will need to educate them on that as well.

Chairman TORKILDSEN. Thank you. Those are very good points. I will just point out, I believe Mr. Alfonso's statistic was that one out of five small businesses do not have computers. Obviously that means that 80 percent do, which I think is a significant number. I would expect that that number would only increase with each passing year. I have no further questions.

Mr. Glover, do you have an additional point to make?

Mr. GLOVER. Yes. Let me just make an additional point. We did a study on the cost of regulations as it applies to small business at the committee's request this past year, and let me just share a couple of statistics out of that, one is the total regulatory burden

on small business was between \$400 billion and \$600 billion. Of that process cost, which is basically paperwork cost, was \$212 billion in 1993.

Now, when you put that in the context, that is far bigger than environmental costs. It represents 40 percent of the cost of regulatory burdens. If you look at the speed with which it is growing, it went from \$140 billion in 1982 to \$212 billion in 1993, a fairly dramatic increase in the process. I think to put the problem in context, we are talking about a lot of money. Minor improvements have a significant return in this regard. I just wanted to share that data with you.

Chairman TORKILDSEN. Yes. As you mentioned, the increase is significant, and the fact that it is somewhere between a half and a third of the total burden right now is also very significant. Clearly, this bill is not going to reduce all the costs of compliance, but it certainly will reduce one significant cost of compliance for the

small business community.

If there is no objection, the record will remain open for 2 weeks for a Member to revise and extend their remarks. With that I thank all the witnesses for their testimony. This hearing is adjourned.

[Whereupon, at 3:10 p.m., the Subcommittee was adjourned, sub-

ject to the call of the chair.]

APPENDIX

PETER G. TORKILDSEN, MASSACHUSETTE CHAIRMAN GLENN POSHARD ILLINOIS RANKING MINORITY MEMBER

Congress of the United States

House of Representatives
104th Congress
Committee on Small Business
Subcommittee on Government Programs
8-491 Ragborn House Office Building
Washington, BC 19515

OPENING STATEMENT

CHAIRMAN PETER G. TORKILDSEN SUBCOMMITTEE ON GOVERNMENT PROGRAMS HOUSE COMMITTEE ON SMALL BUSINESS

HR 2715 THE PAPERWORK ELIMINATION ACT MARCH 27, 1996

Good Afternoon. It is a pleasure as Chairman of the Small Business Committee's Subcommittee on Government Programs to welcome our guests today. The purpose of this hearing is twofold. First to discuss the elements of HR 2715, the Paperwork Elimination Act, which I introduced during the First Session of this Congress and second to hear from the small business community and government representatives on the compliance issues.

The purpose of the Paperwork Elimination Act is to eliminate at least some paperwork. This paperwork elimination would apply to small business, educational and nonprofit institutions, Federal contractors, State and local governments, and other persons through the use of alternative information technologies, including the use of electronic submission, disclosure and maintenance. In addition, this Act more effectively enables federal agencies to achieve the purposes expressed in Chapter 35, Title 44, Section 3501, otherwise known as the "Paperwork Reduction Act".

Specifically, this legislation clarifies provisions within the law requiring agencies to utilize "information technology", to allow individuals with computer terminals and modems the right to use them when conducting business with the government.

This legislation is not mandatory on small business or other users.

Compliance is strictly voluntary for the public. The intent is to make the day-to-day business transactions of the public more cost and time

efficient when dealing with any federal government agency.

I feel it is also important to note that in May of 1995, at the signing ceremony for the Paperwork Reduction Act, the President issued a directive to all federal agencies. That directive was that all agencies were to provide for electronic submission of data, stating that the old way would of course still be available to those who wish to utilize it. The hope is that once the public sees how fast and efficient electronic submission can be, the paperwork burden will be reduced and more individuals will take advantage of this new opportunity.

Again, welcome to our guests. I look forward to hearing your comments on this very important issue.

With that, I will conclude my statement and yield to Mr. Poshard for any statement he may wish to make at this time. 24 .

HOUSE COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON GOVERNMENT PROGRAMS HEARING ON H.R. 2715 THE PAPERWORK ELIMINATION ACT OF 1995

Opening Statement of Congressman Glenn Poshard

March 27, 1996

Mr. Chairman, I appreciate your convening the Subcommittee today to explore an issue that has been at the forefront of the Small Business Committee's agenda during the 104th Congress. Paperwork reduction and regulatory reform have been consistently named by the small business community as top priorities in helping to spur economic growth. Your continued attention to these matters is certainly well placed.

But while I look forward to learning more about the problem, I wonder if new legislation is needed to address it. The Paperwork Reduction Act of 1995, which was signed into law on May 22 of last year, has already initiated a government-wide paperwork reduction process, the results of which are beginning to be analyzed by this Committee. Moreover, some agencies, such as the Environmental Protection Agency (EPA), are attempting greater reductions than required by the law. In a hearing earlier this month before the full Committee we heard about EPA's progress, and though there is still work to be done, I was satisfied that they are making a good faith effort to reduce paperwork and make compliance with regulations easier. Their innovations include greater use of electronic reporting, which is the basis of this legislation. Besides H.R. 2517, there are several other bills pending that desire to reduce government paperwork and regulatory burdens. Perhaps it would be best to learn more about the results of the Paperwork Reduction Act before it is amended or new legislation is created.

Mr. Chairman, that does not take away from your leadership role in this process, for which I would like to thank you. I am eager to hear the insights of our esteemed panel on the particulars of this bill, and I would appreciate any input on my specific concerns. Thank you for much for your attendance and expertise.



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Statement of

Pedro Alfonso
Dynamic Concepts, Inc.
Washington, DC

Regarding H.R. 2715 The Paperwork Elimination Act

Before the House Small Business Committee

March 27, 1996

Mr. Chairman:

My name is Pedro Alfonso, and I am president of Dynamic Concepts, Inc., a small business based here in Washington, D.C. I am an active member of National Small Business United, where I serve on the Board of Trustees and chair the procurement committee. I was also a delegate to the 1995 White House Conference on Small Business. I very much appreciate the opportunity to be here to represent the needs of the nation's small business community and to comment on your very pro-small business bill.

National Small Business United (NSBU) represents over 65,000 small businesses in all fifty states. Our association works with elected and administrative officials in Washington to improve the economic climate for small business growth and expansion. We have always worked on a bi-partisan and pro-active basis. In addition to individual small business owners, the membership of our association includes local, state, and regional small business associations across the country, from the Smaller Business Association of New England to the California Small Business Association.

NSBU was one of the original supporters of the Paperwork Reduction Act, and was greatly encouraged by its strengthening last year. The role that the Small Business Committee played in that strengthening was significant and very much appreciated. But,

Chairman Torkildsen, you have uncovered an area in that law which can be expanded and improved. Your bill provides an excellent addition to the underlying Act.

I have been asked to be here in order to provide comments on H.R. 2715, the Paperwork Elimination Act, sponsored by Chairman Torkildsen. I believe that this bill could significantly improve and streamline the federal paperwork morass in which too many small businesses find themselves. I believe this is the case, not because simply because small businesses will be able to meet federal paperwork requests electronically, but because this requirement will force federal agencies to enter the late twentieth century in terms of technology. This technological advancement will open new doors for, not just the retrieval of information, but also its storage and dissemination. Ideally, agencies will be able to eliminate significant chunks of redundant information. Where regular reporting is required, it will be easy for small businesses simply to report on what is new or changed, rather then refiling all of the information on a regular basis.

Just three weeks ago at a hearing hosted by the full committee on EPA regulations, I understand there was a demonstration of a new project co-sponsored by the Printing Industries of America and the Environmental Defense Fund. This project included computer software that made filing of EPA data quick and easy.

Following this model, the small business owner would use the supplied software on his or her own computer. Once completed, that data could immediately be sent by modem to the agency. With all of that information automatically stored, only relatively quick updates would be required in the future. Moreover, the software can help with overall regulatory compliance. When data is entered, the program could automatically determine what level of compliance is required of that party.

Fundamentally, this move appears to be a win-win for both regulators and the regulated; everyone's lives will be made significantly easier.

Of course, there are other less sophisticated ways to electronically submit data to the federal government, and design and distribution of sophisticated software for paperwork and regulatory compliance—the kind that will really help the most—will be time-consuming and expensive. And H.R. 2715 does not appropriate any money. However, I believe that the significant savings that could be realized in terms of reduced federal personnel (not to mention enormous private sector costs) could certainly offset those costs. Nevertheless, there is a good chance that many agencies could take the "quick and dirty" route to compliance with H.R. 2715 and allow electronic data submission, but not make it user-friendly. While this scenario certainly leaves us no worse off than currently, it must be recognized that only a very small subset of the small business community will use a system that is not designed with their needs in mind. While H.R. 2715 appropriately vests the Office of Management and Budget (OMB) with management oversight to prevent these problems, I also think that it is important for committees such as this one to hold vigorous and pointed oversight hearings. Congressional pressure can produce remarkable results along these lines.

Of course, we also have the opposite concern: that agencies will shift so thoroughly to electronic data that small companies without a technology base will be left behind or unserved. While, on the whole, the small business community is technologically advanced (in some senses, more so than their larger counterparts), one in five small businesses still does not own a computer. While this problem is not a good reason to slow progress on H.R. 2715, it is something to bear in mind, especially in terms of future oversight hearings.

This legislation appears to be a very major step forward for relieving the small business paperwork burden, though I stress again that implementation over the next few years will be paramount. Thank you for inviting me to testify. I look forward to taking your questions and moving this very good bill along.

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3/27/95

Presentation on Paper Work Reduction for Small Business Subcommittee.

First is background, my company is a Small Business. Our focus is narrow, and it is to help business and government to increase productivity and reduce cost using electronic forms and workflow systems based on electronic forms, electronic mail and messaging, database and imaging technologies. We are located in Fairfax Virginia, and our customers include Banks Credit Unions, Mortgage Brokers, Real Estate Agencies, Long Term Health Care companies and local Government. Consequently, paperwork reduction is one of my favorite topics, and I appreciate the chance to speak to a captive audience about it

Forms are 83% of all business communications according to a Gartner Group study which I believe took place in 1993. As an example of the types of savings available to the Government, here are some statistics about forms collected as part of the PAPERWORK REDUCTION ACT. I believe you will find these numbers in the act itself, or in the supporting material behind the act.

As a government we require more than 7000 form or "reports" from the public

The public send back more than 9 Billion responses

After excluding Tax Forms, that number reduces to 7 Billion

The public spends more than 1 Billion hours responding to Government Forms.

These forms are nothing special, they are the everyday fare we find in every agency:

Applications for Grants, Benefits and Services

Compliance Information

Licensing and Permits, and so forth

W hare to get these forms to the public, along with instructions on how to use them.

Then the public fills them out, returns them, and when the responses come back, we have to make sure they were filled out correctly

Finally we process the responses as part of a larger process.

For many citizens, these forms are the primary way they interact with government.

For these kinds of applications, the potential that intelligent forms processing and the Internet holds to improve service and at the same time lower cost is enormous!

How big is enormous? Estimates are about \$22 Billion.

This \$32 Billion is just for

Making

Receiving

Re-≺eying and

Routing of the Paperwork

These savings increase dramatically when we factor in warehousing and dispensing the forms, checking for accuracy and processing the responses

How as Electronic Forms save money and time;

- 1 elimination or reduction of paper forms. No purchase of paper forms, no search for a form you need, since it is slivays available on your PC or network, no inventory of paper forms, saving space costs, eliminating obsolete forms that are thrown away when the forms change, and reducing form management and distribution costs.
- 2 elimination of unnecessary conversations reduction of errors on the form because the intelligence on the form prevents most omitted information, arithmetic calculation errors, wrong spelling, wrong names and addresses (if database lookup is used), answers that are not within the choices available, etc. Intelligent forms have built in controls to prevent these errors.

The intelligent form saves time by automatically populating fields on the same form that require the same information, such as the name, social security number, etc. Additionally, if the form is used as part of a Form Set comprised of multiple forms, the common information is automatically propagated to all the forms in the set. That saves time filling in the forms, and insures consistency among all the forms.

3 automatic routing of electronic mail messages designed into form so all parties that need to act on a form get it, and in the correct sequence. Conditional Routing of the form, or even independent copies of the form can be designed ato it. For example, a rule might be that if the purchase order is under \$500, only the employee needs to work with and a copy routed to the Controller. If the purchase order is more than \$500 it needs to be signed by a manager, and then can go to the Controller. That type of automatic workflow control is capable of being built into the form, and as the obvious cost reduction of eliminating errors, insuring that proper procedures are followed, and there is no ass of forms in the mail.

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- atabase access to assist filling in the form. A user can select from a choice list or enter a key word, such as the endor Name, and using the answer, the form might automatically fill in the DUN's number, Vendor Code, Vendor ddress, phone, fax and Email addresses, and terms. This saves time and insures that the correct information is ways entered on the form.
- atomatic cursor control to move the cursor to the correct part of the form, based on answers already given, saving ne for the user and insuring completeness.
- form can be filled by a person or a program. A software program may already exist which collects the data, and there is a need to be able to interface to the form, and take advantage of the electronic routing. This avoids the need to totally re-implement an existing application, and allows the benefits of electronic forms to be achieved more rapidly
- dynamic subforms provide an ability to create forms dynamically, based on the information that the user is entering This means that even when a form needs to be printed, we can just print the necessary information and eliminate the printing of those sections that are not used, eliminating the need for great books of which the user only uses a page, and tosses out the remainder
- Tracking database to allow analysis of workflow. Tracking the flow of information through the processing provides a means to analyze operations. Using this tool, bottlenecks in the flow of work can be spotted and new procedures "eveloped to speed up operations. Additionally, since there is a record of where each form went, and when it got nere, the often heard phrase "lost in the mail" is no longer supportable since the mail can be set up to retain a record f each form's travels.
- Electronic Signatures remove the need to send paper documents, where electronic signatures are recognized as egal signatures. Since this is already the case for the financial industry, where your PIN (i.e., electronic signature) is ifficient for the bank to issue money at an Automatic Teller Machine, this advance should not be long in coming. Even without full legal recognition, organizations can create policies of their own that recognize electronic signatures as binding, within that organization.

Jsing Electronic Signatures on intelligent forms enables the form to lock-out from change fields that the person signing wants to prevent being changed. For example, if this is a check authorization, at least the payee and amount field would most likely be locked out from change once the authorization is signed. Also, when the manager signs over the Employee Signature, a cascading lock prevents the Employee Signature field from being changed, so there is no capability for tampering

Tectronic Signatures are implemented using the Government endorsed encryption technology, and they are secure.

- Once a form is completed, the data can be used again for another copy of the same form, or as a basis for new requirements. For example, if I fill in a personnel form, and then I need to update the form 1 year later, I can just bring up the original version and update the data that has changed. The unchanged information need not be touched. This saves time. By the way, the old and the new versions of the form can be saved as separate data files for archival purposes, or the new can just replace the old, depending on the need of the agency
- integration with Imaging means that source documents that are scanned in can become part of the form itself and travel with it, eliminating the need to wait for paper mail to catch up. There are many forms that require source documents as verification or as supporting material. For example, an expense account form may be sent around the network electronically, and when it reaches the Controller's desk, the Controller says "I will pay this when I receive your Motel and Restaurant receipts". With electronic forms, the originator of the form can scan in the receipts, and make them part of the form itself. Then the Controller can issue the check immediately

Additional savings come from eliminating the need to send the supporting paper work through the internal or external mail system along with the form itself. The paperwork can be archived immediately, if that is a requirement, while the image travels electronically.

C) Other existing technology provide the leverage which enable the Government and the Public to use electronic forms at a low implementation cost. These technologies include Electronic Mail, Local and Wide Area Networks, Databases, Imaging Groupware and the Internet.

The popularity of Personal Computers and widespread communications technology, such as phone lines, has reduced the cost of technology to consumer, commodity level pricing. The incremental cost of Electronic Forms is also at this low level. For example, the retail list price of JetForm Filler, for a Windows PC or a Macintosh is \$149. BizForms, which is a variation of JetForm Filler which includes forms built in to it, retails for \$49. Turbo Tax is a package that sells around \$29. This is not an expensive technology, and it is relatively easy to add to existing citizen based systems and government systems

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D) El: cronic Forms are platform independent, meaning that once implemented they can be used on PC's, Mac's, UNIX basec ystems, etc. This wide variety of platforms makes them a natural for use in most small business and Government Ager is today.

E) This increasing popularity of the Internet makes it a natural base for Electronic Commerce, both inside and outside the Government, and its low cost make it an attractive tool for Small Business to use. With this system, using platform indept indent interpretive systems such as JAVA, common forms can be implemented once and then be available at zero incremental cost to a user of the Internet. This provides the benefits of Electronic Forms to the public, and enables automatic processing of the captured data by the Government. Government instructions and forms can be delivered to the public at low cost on both sides. One good example of this is the currently available IRIS system from the IRS if you need a tax form and its instruction, all you do is dial that system and download it. This saves time and money because you don't run to either the IRS office, the Post Office or an Accountant to obtain the form you need. And, by the way, the IRIS system never runs out of that one unique form you need at the last minute, and you always get the latest version

One bist point, which is I guess, my sales pitch. As the government gets more deeply into the implementation of the PAPE=WORK REDUCTION ACT, I suggest that it look closely at the firms in Northem Virginia. We have, by some estimates 1/2 of all internet traffic in this area alone. Our technology firms are the leaders in the world in dealing with Electronic Forms and the Internet. In addition to my company, MB Associates, Inc., Jefform Corporation has fit world head anters in Falls Church. America On Line, UUNET, PSI corp and other Internet providers are located there. And the Syster's Integration community of vendors are expert both in Government and Commercial/Industrial applications

Thank you for the chance to present my comments.

Marvin Beriss



Before The

HOUSE COMMITTEE ON SMALL BUSINESS

Concerning the Paperwork Elimination Act of 1996

Presented By

Melvin Gerald, M.D. Member, Commission on Health Care Services

March 27, 1996

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AAFP Washington Office 2021 Massachusetts Avenue, N.W. Washington, DC 20036 (202) 232-9033 (202) 232-9044 (FAX) I am Melvin Gerald, M.D., a practicing family physician in Washington, D.C. Currently I serve as a member of the Commission on Health Care Services of the American Academy of Family Physicians. The Academy is the medical specialty organization representing over 80,000 practicing family physicians, family practice residents and medical students with an interest in family practice. I am pleased to appear before you this afternoon on behalf of the Academy to discuss means to reduce the federal paperwork burden imposed on practicing family physicians and other small business entities.

Although the public generally does not equate a physician's practice with the "small business," that is what it really is. Almost half of the Academy's practicing physician members are in solo practice or in a two person partnership. I work in a clinic with 8 full time physicians, 18 medical assistants, nurses and other clinical personnel, and 30 administrative and operational support staff, half of whom never lay eyes on a patient -- still a small commercial enterprise by any standard. We -- physicians -- are small employers, similar to other small employers in fields other than medicine. We are, appropriately, subject to the same documentation and reporting requirements as any other business entity. We must comply with the same employment regulations issued by the Department of Labor, conduct the same worksite safety programs required by OSHA, observe the same disposal rules promulgated by EPA, and perform the same quarterly ritual with the IRS. And, we must record, submit, and store evidence of our compliance.

We are unlike other industries in that health care is both a service and an information industry, and is becoming more information driven every day. Every action a physician takes on behalf of his patient, from the first moment of their first encounter, has an information component to it. Every action must be recorded, documented, attested, filed, submitted, justified, resubmitted, and stored in accordance with an incomprehensible tangle of standards, regulations, and third-party requirements. Medicine has become the great paper chase. Unfortunately, all the paper does not help our patients receive better care or protect them from harm or lower the costs of care. Rather, it takes away from the time we have to care for patients. A recent Academy survey found that family physicians spend, on average 20 percent of a 60-hour work week on administrative tasks. These administrative tasks often are the direct result of federal regulations and their attendant documentation requirements.

Over a third (35.5 percent) of family physicians are in solo practice, an additional 12% are in twoperson partnerships, and another third practice in small to medium-sized groups. These practices tend to have very high overhead and limited staff resources. They provide medical care in rural America as well as in urban and suburban areas. The in-service and administrative structure taken for granted to exist in larger organizations such as hospitals, simply does not exist in these physician groups. Consequently, each new administrative requirement measurably increases the costs of providing health care services and diverts resources from direct patient care.

Over the years, the layers of federal regulation and their attendant paperwork burden have had a profound effect on the practice of family medicine. Medicare, which typically covers as many as 40 percent of a family physician's patients, is one of the most complex laws in the land, with

literally thousands of pages of regulations, instructions, directives, and forms. The Physician Payment Review Commission noted in its 1994 Report to Congress that increased paperwork was the second most frequent complaint registered by physicians with respect to the Medicare Fee Schedule. Similarly, a 1993 study of family physicians' satisfaction with their practices concluded that "The number of physicians considering external regulations and paperwork as problematic has increased from a bare majority [in 1983] to almost unanimity [in 1993.] According to this study, regulations by government agencies and the amount of paperwork involved in medical practice are now felt to be moderate to large problems by 90% of practicing family physicians. As you might expect, the acuity of bad feeling about government-sponsored paperwork goes up as the size of physician practices goes down.

We commend the House Committee on Small Business and Chairman Meyers for their tireless efforts to reauthorize the Paperwork Reduction Act. The Paperwork Reduction Act promises the public that the Government will check the need for information before anyone is asked to provide it or maintain records. The Act is intended to minimize the public burden of providing and maintaining information that the government needs to deliver services. The reports clearance process established under the Act requires agencies to demonstrate the necessity of the data they wish to collect, its practical utility, and the imposition of the minimum burden possible. OMB's Office of Information and Regulatory Affairs is authorized under the Act to prevent the imposition of needless paperwork requests upon the public.

We are grateful for the opportunity to comment today on the "Paperwork Elimination Act of 1996," sponsored by Representative Torkildsen. The Paperwork Elimination Act would further decrease the paperwork demands by the Federal government by advancing the use of alternative information technologies to satisfy agency information collection requests. It would require the Director of OMB to promote the use of electronic submission, maintenance, and disclosure as an option for entities complying with federal regulations and would require individual agencies to make this option available to those of us on the recieving end of information requirements. Appended to my written testimony are examples of the kinds of information collection and recordkeeping that the federal government imposes on practicing physicians. At first blush, it may not seem that the issues raised therein are amenable to redress through alternative forms of information technologies. However, I want to assure this subcommittee that the steps you are taking to require federal agencies to accept electronically-submitted information will ultimately have a profound and very positive impact on physicians' ability to satisfy those requirements.

Our health care system is changing and evolving rapidly. It is spinning off new delivery system configurations as payors and providers who once functioned in relative independence from one another now merge into HMOs, provider-networks, and consortia. Behind this movement toward greater integration is a clear imperative from the marketplace: health care must be delivered at demonstrable value, at lower cost, and with more direct accountability. At the heart of this movement -- what makes it possible -- are the emerging information systems that enable an assessment of quality and health care outcomes. Measuring what it is that health care provides enables doctors and hospitals to sort out effective from ineffective care, plans to select cost-

effective providers, and payers and consumers to discern levels of quality among health plans. Ultimately, it is information — demanded at many different levels from many different market players — that is driving innovation in health care. Those innovations are, in turn, yielding more collaborative approaches to the collection and management of health care data and information.

For example, the disparate parts of health care systems — doctors, pharmacists, hospitals, insurers — are now pooling and sharing their patient data across settings and over time. Individual patient medical records can be stored on a central computer and accessed instantaneously by whomever the patient is seeing. The patient's history, and the reason for clinical decisions made along the way, are retrievable with the push of a button. Similarly, individual provider performance on specific quality indicators over time can be tracked by computer, and compared to peer performance. Billing practices can be monitored and outliers identified.

At the national level, all segments of the industry are at work on developing data and content standards for the electronic transmission of health information. In the private sector, the information revolution is well underway. We expect that in the near future, we will see a seamless national health care data system based on encounters and payments at the patient, provider, and health plan levels. Moreover, we would expect that the agencies which regulate health care services in a physician's office would be able to find everything they need to know in these electronic data sets.

In the interim, there is much work to be done. It is the Academy's hope that the "Paperwork Elimination Act" will stimulate governmental agencies involved in the regulation of health care toward accelerated work on standards for the electronic collection and transmission of health care information. The Department of Health and Human Services should be encourage to pursue common informatics standards for Medicare fiscal intermediaries and carriers, state Medicaid programs, federally qualified HMO's and other payers. Barring radical changes in the financing and delivery of health care, the vast majority of physicians and other providers will continue to treat patients covered by a variety of health benefit plans, including a variety of public plans. Thus, providers are likely to need to communicate with a variety of payers, utilization review agents, and quality assurance entities. Health information systems that must contend with numerous incompatible requirements from payers are more costly for providers to acquire. In addition, providers faced with incompatible requirements must spend more time and money to train staff to handle more complex systems. (For this reason, the Academy has long advocated that the health care industry move to a single health insurance claim form). How much easier it would be if I, as a physician, could enter a standard set of data about each patient and each office visit into the computer in the same format so that I could collate data fields in whatever form the requestor required -- across patients, across specific services, by date, by outcome, by insurance status, by Medicare visit code -- and send it off.

Standardization of the data required for various health care payment, quality assurance, and regulatory functions will facilitate the movement toward a paperless health care system. That, in turn, will result in substantial cost savings not only to physician practices, but to the health care

system as a whole. The magnitude is suggested by HCFA's own experience with computerized claim forms. According to the agency, the Medicare/Medicaid common claim form 1500 now imposes "only" 52 million burden hours on the public (providers), down 21 million burden hours due to a substantial increase in percentage of claims submitted electronically. Similarly, 95 percent of all HCFA 1450 forms are submitted electronically, and represent 975,000 public burden hours. By comparison, the 5 percent of claims that are still submitted in hardcopy represent 543,000 public burden-hours. Clearly, the industry has much to recover from an accelerated push toward administrative simplification through electronic data submission.

Federal leadership in the development of a common architecture for health care data and information is essential. Standardization of data content is not just a matter of identifying which data elements should be collected. It also means agreeing on the definition and codes for those data elements. Currently, when payers appear to be asking for the same data elements, they could be asking, in fact, for very different information. For example, to identify a physician, some payers want the Medicare physicians number, while others may want the physician's state licensure number or federal tax identification number. Payer requirements for the collection of other data elements can be equally diverse and confusing, such as different rules for diagnosis and procedure coding or different methods for determining entitlement information. These differences add up to enormous costs for providers. When similar information must be communicated for more than one purpose (e.g., patients name is needed for benefit eligibility determination, billing, and other purposes), formats for this information must be compatible.

The work of the American National Standards Institute (ANSI) and a host of other organizations in this regard is most encouraging. With the federal government's participation, they are solid demonstrations of what can be achieved in public-private partnerships. However, it appears to us that since the demise of national health care reform, these efforts have lost some of their momentum. With prompting from this Committee, perhaps the agencies will recommit themselves to the goal of paperless records and transactions.

Finally, there are two specific issues I would like to bring before this committee for your consideration. The first involves the enforcement of the Paperwork Reduction Act's requirements on non-governmental entities that are acting on behalf of federal agencies. Unlike other small businesses, physicians interface with the federal government primarily through federal contractors, including Medicare Carriers and federally qualified HMOs. It is by no means clear that these intermediaries routinely comply with the PRA clearance process prior to issuing another form that I or my staff has to fill out. For example, my practice participates with 15 HMOs and 20 PPOs. Some are federally qualified plans serving Medicare or Medicaid beneficiaries, others are not. They all require information, but the federally contracted plans require significantly more information than the others. The difference is so significant and so consistent, I can only conclude that HCFA is holding the plans accountable for certain information that they can only obtain from their participating physicians directly. For the sake of program integrity and beneficiary protection, that additional information may be an appropriate requirement. But it means I have to fill out dozens of forms and mail out reams of documentation because no one thought to ask the federally qualified health plans to coordinate their information collection activities. To my

mind, parties collecting information on behalf of the federal government should be subject to the requirements of the PRA. Even when forms do sport an OMB Circular number, they often are redundant requests for information previously submitted on another form, for another slightly different purpose -- a circumstance the PRA review process is supposed to relieve. What applies to HCFA applies to its contractors as well: simplification and standardization in the way health insurance claims are processed, patient records are handled, utilization review is conducted, and regulatory and administrative oversight are enforced can bring about significant cost-savings.

The second issue I'd like to raise with you is that of physician participation in the review of information collection requests. In addition to strengthening the Paperwork Reduction and Regulatory Flexibility Acts as this Committees is proposing, the Academy strongly recommends that the input of practicing physicians be brought to bear on proposed regulations and information collection requests while they are still in the internal development process.

To implement this recommendation, we suggest that the role of the Practicing Physician Advisory Committee (PPAC) be expanded to include review of information requests that would impact on medical practice. The PPAC would analyze the information request from a cost-effectiveness standpoint, evaluate the clinical appropriateness of the request, and make recommendations for elimination, reduction or refinement of unnecessary, inappropriate, duplicative, ineffective, or overly costly paperwork requirements. The Practicing Physician Advisory Committee (PPAC) was created by Congress to review new regulatory proposals and provide the input of practicing physicians on implementation issues. While a good idea, the Committee has not been properly utilized by HCFA. Until recently, the agendas of the Committee have been relegated to relatively minor items, with the real issues of concern to physicians not being addressed. The Committee has the talent in its membership to facilitate resolution of many of the problems confronted by physicians in dealing with the paperwork requirements imposed by the Medicare program. HCFA and OMB should be required to use the committee to review all major Medicare information collection requests, as well as proposed regulations.

To summarize, a multitude of complex regulations, each with its own paperwork requirements, have developed under the current health insurance system. The administrative labyrinth frustrates patients and physicians alike, can hinder prompt delivery of care, and contributes significantly to the cost of health care. For family physicians, bringing about administrative simplification also means that they will someday be able to devote to the care of their patients the significant time and resources they now expend on repetitive, confusing administrative "hassles" and duplicative paperwork.

Change is not possible overnight, but the health system is moving in the direction of greater coordination and increased efficiency through electronic information exchange. Without a mandate, without incentives other than cost-savings and simplicity, the percentage of physicians whose practices submit claims and have electronic billing capabilities has skyrocketed. We have no doubt that trend will continue. The marketplace and competition are creating this movement. The government's vigorous leadership will encourage it.

Once again, I appreciate the opportunity to appear before you today. Federally-imposed paperwork is adding significantly to the costs of operating a small family medicine practice. It presents a growing obstacle to the attentive, cost-effective medical care that is family medicine's hallmark. I and my professional colleagues appreciate the efforts of this committee to seek more effective and responsible ways to minimize that burden, and we would appreciate the opportunity to continue to work with you in that endeavor.

APPENDIX

Medicare Claims Resubmissions

Medicare is one of the most complicated and confusing programs administered by the federal government. HCFA has attempted to resolve various regulatory burdens but much more needs to be done. Each year, physicians are faced with increased layers of requirements and inconsistent instructions. Not only are these regulations cumbersome and expensive, they are often badly conceived from the perspective of view of patient care. Exceptions from Medicare's rigid rules, even for reasons of medical necessity, are hard won, and must in every case be justified with exhaustive, often redundant, documentation. The cumulative expense and frustration is such that many physicians are reluctant to accept new Medicare patients into their practices.

Permit me to share a specific example. A physician, concerned about his patient's history of borderline diabetes, performs a urinalysis to check for protein levels. The physician checks the appropriate diagnosis, "Diabetes," and submits a bill to Medicare on the patient's behalf. However, Medicare rules state that a urinalysis is a reimbursable test only when the diagnosis relates to kidney function or a urinary tract infection. Somehow, the carrier's computer is not programmed to link up "urinalysis" with "diabetes." The response comes back from Medicare in the form of a letter which instructs the physician that there was no justification for the test he performed on his patient, and the bill will not be honored. The physician writes a letter to explain that the test was, indeed, necessary for proper medical management of this particular patient, attaches appropriate documentation from the medical record, and instructs his office staff to log and send the letter. Phone calls from the carrier requesting additional documentation follow, and computer printouts are reviewed. Eventually the claim is paid. Medicare's reimbursement for a urinalysis provided in a physician's office: \$5. This vignette is typical of what happens in small family physician's offices many times a day.

If all the relevant information were contained in a single electronic record, the request for review and accompanying documentation could take a matter of seconds, rather than hours.

Rejected Claims

HCFA's requirements for resubmitting Medicare claims that are rejected because of simple errors are disproportionately time consuming and expensive. If a patient who is being treated for hypertension also mentions that she is having trouble hearing, and they physician discovers and removes earwax, Medicare requires that a modifier be added to the visit code for hypertension to signal that a secondary service has been provided. If the physician (or his billing office) fails to include the modifier for the principal service, Medicare will deny one or the other charge. If the physician resubmits the claim for payment, he cannot simply make the correction and resend the same claim. He must pull the patient's charts, make copies of that record of the encounter in

question, attach those to the bill, log the status of the transaction in his own books, and then post the package back to the carrier. For the small charge items typically provided in a family physician's office, this process represents a significant expense in terms of time and resources, while the account remains due. It is another instance in which paperwork robs dollars from patient care.

Clinical Laboratory Improvement Act (CLIA)

CLIA is a particularly apt example of how cost-benefit analysis would improve regulatory activity of the health care sector, not only in the evaluation of information collection and storage requirements, but also in terms of regulatory drafting by Congress and the agencies. As I'm sure members of this Committee are aware, CLIA was created in response to highly-publicized problems with cytology testing in a commercial lab, and now regulates the full scope of medical testing, including testing done in physician office labs. The net effect of this statute and its implementing regulations has been decreased access to care for Medicare beneficiaries and an increased cost of tests. It is our most fervent hope that the combination of legislative and regulatory reform initiatives in the various Contract bills will help prevent this type of inappropriate legislation in the future.

The requirements imposed on any physician office that maintains a laboratory for the benefit and convenience of patients are extraordinary. Under CLIA, physician office laboratories which perform only simple tests are waived from the law's proficiency testing requirements. However, "waived" labs are required to pay a \$100 fee each year to register their waived status with the federal government. Physicians have never understood why a waived lab doing waived tests and therefore exempted from lab testing requirements must register with HCFA.

CLIA certification and documentation requirements for non-waived physician office labs are even more formidable. For example, as a matter of sound medical practice, physicians always record patient tests and results in the medical record. However, CLIA requires physicians to maintain a separate office record in which all laboratory tests and associated information are to be logged in chronological order. Such a requirement may be necessary in a centralized lab that has no other record of the patient, but for the physician's office, it simply represents extra, duplicative paperwork with no practical or clinical utility, necessary to produce and keep around only in case the auditors drop by.

But perhaps the biggest waste of paper is CLIA's requirement that physician office labs have a written manual that describes in detail the procedures used to perform office-based testing. The manual must include procedures for sample collection, meaning, for example, that the physician must clearly document how his nurse is to instruct his patients to negotiate the dixie cup while sitting. Since physicians offices already have all of the information required by CLIA, the effect of requiring a separate procedures manual is to force physician office staff to retype existing information and store it in a new location. In a 1992 Fiscal Impact study of CLIA, Levine

Associates estimated the administrative costs of recording data, maintaining files, producing manuals, hiring additional personnel to handle the additional administrative tasks, time of existing personnel, etc., to approach 25% of the total costs of CLIA implementation. These kinds of requirements render the physician office labs financially non-viable, resulting in the closure of such labs.

As a direct result of CLIA regulations, a 1993 family practice survey found that a large number of family physicians no longer provide the level of in-office testing they believe is necessary to serve their patient populations. The number one reason cited was "Too much government red tape". Instead, many physicians now send their patients across town (or out of small rural towns) to large hospital or commercial labs for any testing, at a substantial increase in cost to both Medicare and the beneficiary.

OSHA Blood-Borne Pathogen Standard

OSHA Blood-borne disease regulations have imposed massive regulatory and paperwork burdens physicians. These regulations require physicians' offices to develop and annually update an office plan for preventing exposure of office personnel to HIV or TB. The plan must include a training program for all employees, the content of which is specified in fine detail in the regulations. Training must be annually updated, regardless of whether changes have occurred in office personnel, infection control procedures, or patient or employee risk factors. Training records must be maintained for three years and must include dates, contents of the training program and/or a summary, the trainer's name and qualifications, names and job titles of all persons attending the sessions. Failure to comply with any of these requirements can result in a \$10,000 fine.

OSHA's documentation and record-keeping requirements impose a considerable burden on small physician practices and add significantly to administrative costs. Whereas large medical groups and health care institutions can may be able to identify a nurse or other qualified health professional to take responsibility for OSHA coordination and compliance, in small physician offices, the physician him or her-self is often the only individual with sufficient expertise to update the office plan, conduct the annual training sessions, and manage the records. Physician time is expensive, as is the resulting "down time" for the rest of the office. The substantial time and expense involved in meeting OSHA's documentation requirements could be far more effectively devoted to patient care services.

The OSHA standard also requires that employees' personnel records be retained by the physician's office for 30 years after the individual leaves employment. Such a requirement is impractical for a small personal service business and far exceeds and recordkeeping routines undertaken within medical practice even for patients. As a practical matter, it poses added office overhead expense for a small office with limited long-term storage capacity.

We hasten to add that our complaint stems not from our failure to recognize the need for careful precautions against blood-borne pathogens, particularly in health care settings, but rather from

frustration and disappointment that OSHA's overly burdensome and expensive approach to safety is, in this instance, entirely inappropriate to the nature of the risk. Guidelines developed by the Centers for Disease Control and Prevention that are grounded in good medical science will do more to halt the transmission of HIV/TB than all of the federal government's documentation requirements combined.

Nursing Homes

Current regulations governing the medical management of nursing home patients have generated an enormous amount of expensive and time consuming paperwork not only for physicians, but for nursing home administrators, nursing staff, and pharmacists as well, and have added significantly to the cost of caring for nursing home patients.

For example, if a nursing home patient should happen to fall, for whatever reason, HCFA requires that the patient's physician be notified whether or not the incident was significant from a clinical perspective (that is, resulted in bruises or more serious injury). Though well-intentioned, this requirement is far too broad and consequently generates an enormous amount of paperwork. First, the nursing home staff must document the spill, then, it must notify the physician and document having done so. The physician must then document the information he has obtained from the nursing staff in the patient's chart. Several days later the physician receives written documentation from the nursing home that also needs to be filed. Understandably, physicians question the need for so much paperwork, particularly in those instances in which a fall has not resulted in any injury to the patient.

Another set of regulations stipulates that psychoactive agents may be administered to nursing home patients only if their indication clearly documented in the record. That is clinically appropriate. Under the law, however, it is the responsibility of the nursing home to ensure that the appropriate documentation exists. Non-medically trained nursing home administrators do not have the expertise necessary to make such an assessment, and therefore typically hire an independent pharmacy service to monitor patients' clinical records. The law specifically stipulates that the pharmacist may not question the patient's care, only the documentation of the care. Through poorly designed regulations intended to protect Medicare patients from psychoactive restraints, a layer of administrative personnel at the pharmacy level has been added to do medical record reviews to ensure that medical care is being documented appropriately, and is contributing to the already exorbitant costs of long-term care.

Medical Necessity Documentation for Lab Services.

HCFA is currently considering a new requirement for physicians to supply documentation of medical necessity when ordering more than 12 automated lab tests. This is a misguided approach

to a recent fraud case of labs billing for more tests than the physicians ordered. HCFA's proposed "solution" is to penalize physicians rather than the few labs who were the real culprits.

Automated lab tests are frequently conducted in panels or packages in which several tests are performed concurrently. It is less expensive and more efficient to order a multi-panel test than to order individual tests a la carte.

Some time ago, several reference labs were accused of billing for tests that were not ordered. There were instances when a physician ordered a panel of tests, and the lab unbundled the services, submitting the charges to HCFA as many different tests. The Practicing Physicians' Advisory Council explored this problem and recommended that HCFA establish panels that would be uniform for HCFA, uniform for the M.D.s ordering the tests, and for the labs billing for them. This recommendation would have addressed the problem in a relatively straightforward manner.

However, under the new rules, physicians and laboratories must document the "medical necessity" of each lab test ordered. This requirement will impose massive new record-keeping requirements on the physician community. It is also unreasonable from the perspective of clinical medicine. Laboratory testing is often a tool to provide a missing piece of the medical puzzle. Our patients do not always arrive on our doorsteps with a known diagnosis — A patient does not usually come into an office and say, "Doctor, test me because I have lymphoma". But she might complain of fatigue. How is a physician to prove "medical necessity" when ordering tests on a patient who says she's tired? Moreover, patients often have multiple disease processes occurring at the same time or are borderline for one or more diseases. It is simply not appropriate for Medicare carriers to second-guess a physicians' professional judgement. If physicians are required to reduce the number of tests ordered, or confine the tests ordered to a specific disease process, the opportunity for early detection will be diminished.

The Health Care Financing Administration says Medicare could save \$60 million by implementing these regulations, however, the administrative costs associated with the change are likely to far exceed the costs of any "unnecessary" testing.

Furthermore, the draft instructions allow each carrier the discretion to require documentation for fewer than 13 tests if it believes it is necessary. This causes us grave concern -- the lack of national guidelines for enforcement of documentation requirements has always lead to mischief in the past, and provides no accountability through which medical professionals can seek recourse on behalf of their patients against arbitrary and medically unsound determinations.

If HCFA's new Medicare Carrier Manual instructions are implemented, then we will have a sad example of an entity set up by Congress to reduce the hassle factor -- PPAC -- that came up with a mutually agreeable solution, only to be subverted by HCFA's more bureaucratic approach. HCFA's legitimate utilization concerns could be more effectively addressed by focusing on the outliers (i.e., profiling the physicians and labs that are performing excessive numbers of tests). The Academy regards these carrier instructions as a good test of the scope and strength of the

Paperwork Reduction Act. We will be watching to see whether OIRA and OMB assert jurisdiction with respect to these instructions, and if so, to what effect.

Certificates of Medical Necessity

Durable Medical Equipment Regional Carriers (DMERC) are using eleven new carrier-developed Certificates of Medical Necessity (CMNs) for different pieces of durable medical equipment. Physicians are required to complete these forms and are held accountable for their contents by HCFA. However, some of the questions on the CMN are clearly not within the professional training or competence of most physicians. For example, a series of questions relating to air fluidized beds requires the physician to provide technical input on the electrical and structural capability of the patient's home to handle the bed. Another question requires the physician to certify that the wiring in a patients home is adequate for the use of a home oxygen concentrator. Physicians do not have the ability to make judgements about electrical or structural engineering. We find it notable that none of the CMNs were developed in consultation with the medical profession or approved by the federal government.

Home Health

Medicare beneficiaries receiving home health care services must be recertified in regard to the need for those services every 60 days, regardless of the patient's health condition or other circumstances. On alternate months, HHAs must also submit a progress note indicating whether the patient's condition has changed. Both forms must be received and documented in the patients record by the physician, and the physician must order either a change in or renewal of the patient's treatment plan. The paperwork associated with these recertification is massive and burdensome for both the home health agency and the ordering physician. What these requirements fail to recognize is the tremendous variation in patient need. Some patients do not require home health services for even as long as thirty days; many others will require it for the rest of their lives, and so much is known from the very first day the services are ordered. Rarely do these monthly reviews results in any affirmative action on the part of the physician with respect to the patient's plan of care. Almost all of the orders' changes occur because a nurse calls with an acute issue that is dealt with on the phone in real time. Yet, because of all this unnecessary and duplicative paperwork, home health agencies spend up to three quarters of their time completing forms and only one quarter actually taking care of patients. We strongly doubt that such requirements would pass any cost-benefit analysis.

We note that one of the screens to be addressed by proposed information requests under the PRA is whether the requested information could be collected with less frequency than proposed. Regarding home health certifications, HCFA's justification to OMB under the PRA states simply, "The collection of this information less frequently would result in a lack of uniformity in HHA claims determinations and the continuation of payment for unnecessary or inappropriate home

health services furnished to Medicare beneficiaries. We believe that submittal of the POT and MIF forms every 60-days is an irreducible minimum." As mentioned above, the inflexibility of this requirement bears no relationship to clinical reality. It's logic is geared more toward bureaucratic needs than the needs of patients. Moreover, while the justification estimates that the "burden" of the bi-month forms amounts to 28 minutes for one form and 15 minutes for another, for a total burden of 2,916,922 hours across all of the nation's 6130 home health agencies which are Medicare providers, nowhere is the administrative burden on the physician considered or estimated.

Notwithstanding the fact that physicians and nurses alike feel the "burden" of these forms is underestimated, and given the cost of health professionals' time, it would make more sense for HCFA to enforce program integrity through periodic retrospective review of cases, in which providers are compared and those that show themselves to be outliers in terms of the amount of services they're providing each client are more closely reviewed. Who knows, maybe they're doing things better?

Testimony of

Jere W. Glover

Chief Counsel for Advocacy

of the

United States Small Business Administration

before the

Subcommittee on Government Programs

of the

Committee on Small Business

House of Representatives

March 27, 1996

Good Afternoon Mr. Chairman: It is as always a pleasure to appear before this distinguished body to address matters of importance to the small business community. As you know, the Chief Counsel's role, by statute, is to represent the views and interests of the small business community before Congress and other federal agencies.

The streamlining of government programs, policies and procedures has been long in coming. The federal regulatory process has definitely been placed on the front burner by Congress and by the Administration and I, for one, would like to keep it there.

It is clear that technology is opening opportunities for reduced regulatory burdens on small business - the focus of today's hearing. Before proceeding, however, to my comments on the proposed legislation, I think it would be useful to review:

- the need for additional changes in the regulatory burden, and
- what is happening with technological initiatives in federal agencies.

Regulatory Burden on Small Business

¹ The opinions in this testimony are mine and do not necessarily represent the views of the Administration or the Small Business Administration.

For the most part, federal agencies have been increasing their efforts to reduce regulations and the attendant paperwork burdens, making compliance easier. Many of them have learned to work smarter in a customer-oriented environment. However, there are still too many agencies using a broad brush to portray the impact of their actions on small firms as insignificant.

Businesses in the United States face a daunting burden in complying with government regulations. I do not need to tell anyone here, that the paperwork-regulatory issue remains a major issue about which small businesses complain. This was a major issue at the 1980 White House Conference on Small Business and again at the 1995 conference, which underscores the importance of the Paperwork Reduction Act of 1995² and its implementation.

A study funded by the Office of Advocacy in the Small Business Administration indicated that nearly two-thirds of the firms canvassed nationwide firmly believe they face more than just minor regulatory burdens and a quarter of the firms described the burdens as substantial.³ Firms with fewer than 50 employees report the largest shares of their revenues are used to pay for their regulatory burdens. In fact, firms with 20-49 employees

² P.L. 104-13, 44 U.S.C. Chapter 35.

Thomas Hopkins and Diversified Research, Inc., "A Survey of Regulatory Burdens", June 1995. Performed under contract No. SBA-8029-OA-93.

appear to be most affected, spending nearly 20 cents of each revenue dollar earned on government regulatory compliance.

A subsequent study indicates that the average small firm with under 20 employees spent approximately \$5,500 per employee to comply with federal regulations in 1992. By contrast, firms with 500 employees or more spent, on average, \$3,000 per employee. In the aggregate, regulatory compliance costs are now in the range of \$420-627 billion (in 1995 dollars). Regulatory compliance costs are large by any reckoning and smaller firms are especially burdened despite a variety of efforts over the years to provide exemptions keyed to the size of businesses.

Electronic Data Interchange (EDI) and Electronic Commerce (EC)

There is no doubt that a shift toward electronic reporting (and recordkeeping) is bound to alleviate a considerable amount of the burden created by government needs for information. While I admit to being no "hacker" with a computer, I am truly excited by the prospects offered by the power of electronic communication. I believe that Electronic Data Interchange (EDI) has the potential to make government programs more accessible, reduce red-tape and paperwork, thereby saving time and money for both small business and the government. Implemented properly, the possibilities and

Thomas Hopkins, Rochester Institute of Technology, "Profiles of Regulatory Costs", November 1995. Performed under contract No. SBAHQ-95-M-0298.

opportunities offered by this technology are excellent and, perhaps best of all, anyone with a personal computer should be able to participate.

As everyone here is probably aware, EDI is the computer-to-computer exchange of documents in electronic form between one organization and another, either within a company or between companies. The use of this medium is becoming an integral part of the way companies operate on a day-to-day basis across industries and government. The projected market for Electronic Data Interchange (EDI) products and services is expected to grow to over \$3.0 billion by 1997. By the year 2000, it is estimated that as much as 70 percent of American businesses will be using EDI.

Electronic Commerce (EC) is the conduct of business through the use of EDI between organizations.

Early electronic systems date back to the 1960's. Leaders in electronic commerce development include large retailers, such as K-Mart and Sears in retailing, General Motors in the automotive industry, and McKesson in pharmaceuticals. These firms developed proprietary data networks between themselves and trading partners to exchange business documents electronically, such as purchase

Ferguson, Daniel M. and Dubos J. Masson, 1993. "The State of EDI in the U.S. in 1993." EDI Forum, No. 4, pp. 8-11.

orders, invoices, and shipping notices. As the use of electronic exchanges spread to other industries, standardized industry-specific formats were developed. Subsequently, the widespread availability of EDI software and services resulted in third-party commercial electronic networks and service bureaus, enabling further diffusion within and across industries during the 1980's and 1990's.

Many small and medium sized firms began using electronic transfers only because they were requested to do so by their major customers. A recent study of 255 small and medium-sized companies using electronic data systems in manufacturing, for example, reported that 75 percent of respondents cited customer pressure as the critical factor in their decision to implement electronic commerce. Large companies have, in many cases, dictated to their suppliers that they must adopt electronic data systems.

EDI With the Federal Government

As for communicating with the Federal government, a major problem faced not only by small businesses, but all organizations, aside from the technology itself, is the sheer volume of information confronting them. Despite promises of increased efficiencies,

Morell, J.A., W. Neal, and V. Fries, "EDI in Manufacturing: Small and Medium-Sized Companies," <u>EDI FORUM</u>, Vol. 8, No. 3, 1995, p. 24.

lower costs and ease of access, many small firms have been very reactive, rather than proactive, to the electronic highway.

For many small business men and women, whose technical expertise is marginal, computer technology can be a very intimidating process. We believe many small firm owners are passive about the entire process because: (a) they believe they cannot afford the computer capability; (b) they believe that they cannot afford the time to be trained in the subject area or that they cannot support an information systems employee to handle their electronic commerce; and/or (c) they are simply overwhelmed by the entire instruction sequence or the choices offered by these systems.

The Small Business Administration is trying to address this issue and you will hear more about its efforts from my SBA colleague accompanying me here today.

Although electronic data systems have been used by the government for inventory control and logistical support from large business suppliers since the 1950's, the bulk of smaller government procurements will be offered on-line for the first time over the next decade. We firmly believe that once small businesses experience the initial communication, their concerns will vanish. This is expected to occur particularly if, as electronic systems become more widespread in government, federal agencies work

closely in partnership with the small business community to provide them with the training and assistance needed to enable them to adopt electronic commerce practices.

Finally, in our desire to promote electronic data systems, we need to keep in mind that small firms should not be coerced into implementation of electronic data interchange because of the concomitant cost which can range from a few hundred dollars to thousands of dollars. Small firms need to be given the choice as to which cost to incur -- equipment or time -- until the benefits of one outweigh the other.

TECHNOLOGICAL INITIATIVES IN FEDERAL AGENCIES

In preparation for this testimony, we did a quick survey to determine what agencies were doing now relative to electronic data interchange (EDI). The initiatives we identified fall into three categories:

- a) general information services;
- b) procurement programs; and
- c) reporting/data collections.

It might be helpful to review these briefly, keeping in mind that this list may not exhaust all that is happening in federal government.

General Information Services

The U. S. Business Advisor is the government's major initiative to provide a one-stop link to government information and services available to small businesses.

In June 1995, the President asked the Small Business

Administration to co-chair an effort to "help create a government that uses information technology to interact with and serve its customers on their terms." Working with the Vice-President's National Performance Review, and through the hard work of an interagency task force, a one-stop, electronic link to government information and services was built to help businesses succeed.

On February 13, 1996, the Vice President unveiled the initial phase of the Business Advisor. For the first time in our nation's history, a business owner can contact a single "Home Page" on the Internet that permits access to all federal government departments. The information is also organized in the format/structure requested by the business community. Over 200 business owners attended focus groups and told government representatives how they wanted to access this information. The Business Advisor offers some electronic transactions on the Internet, including the ability to download government forms (tax forms, loan applications, contracting opportunities), the Commerce Business Daily, business software, laws and regulations,

information on credit, international trade, grants -- the list goes on. Incidentally, for your general information, the location of Business Advisor is http://www.business.gov.

The Small Business Administration has been involved in EC/EDI outreach and training activity since August 1994. Our effort has included train-the-trainer sessions for SBA personnel, as well as direct training of small business owners.

In addition, we have created an electronic resource for EC/EDI information on the SBA's bulletin board, SBA Online and on the SBA Home Page on the Internet. Through these electronic sources, small businesses can:

- learn about training seminars being offered by public and private sector organizations throughout the United States,
- obtain the list of small business friendly banks in their state,
- 3) file requests electronically for mentoring sessions with the Service Core of Retired Executives (SCORE), and
- 4) obtain a wealth of other business, regulatory, financial and marketing information.

Small businesses can also gain access to the list of certified Value Added Network providers, discover which agencies are currently purchasing commodities through electronic data interchange, and read the answers to the twenty most frequently

asked questions about EC/EDI.

The information is updated on a regular basis and new information, education and training has provided many thousands of businesses with basic information about EC/EDI and created an awareness of the Federal government's implementation of a paperless procurement system. As an example, all Small Business Innovation Research (SBIR) information for the eleven funding agencies is now on the SBA Home Page, as well as information for minority and women business owners.

There is no doubt but that these electronic sources are being used. In the 20 months of its existence, the SBA Internet Home Page has had a 100% increase every six months in the number of files accessed -- now over 400,000 per week!

The Department of Labor provides information, publications, new regulations, enforcement actions, and developments on safety and health issues through their electronic bulletin board.

The Postal Rate Commission has devised an electronic bulletin board which contains Commission orders, notices and opinions as well as other documents and other electronic data filings. One can obtain the nine-digit zip code for any location in the country instantly from their Internet Home Page.

The Department of Agriculture has moved toward a program entitled, "Electronic Benefits Transfer" (EBT) in partnership with the states. It involves direct deposits in personal accounts for recipients of social security, unemployment benefits, aid to families with dependent children and food stamps. Recipients can then utilize EBT cards to access their benefits through automated teller machines or grocery stores.

Procurement Programs

In federal procurement markets, the use of electronic commerce is expanding significantly.

The President's Memorandum of October 26, 1993, Streamlining
Procurement Through Electronic Commerce, encouraged all agencies
to employ electronic commerce to improve access to federal
contracting opportunities and increase competition.

The Federal Acquisition Streamlining Act of 1994 established the Federal Acquisition Computer Network -- FACNET -- which requires the government's paperwork-driven acquisition process to evolve to an expedited system based on electronic data interchange. When fully operational, the shift from paper-based to computer-based communications between the government and its suppliers will expedite processing as well as provide quicker and broader

information to potential and existing vendors.

In addition, electronic markets should make it easier for government agencies to comparison shop and arrange just-in-time deliveries among a large number of vendors.

The government's FACNET system is currently under development. A number of agencies, especially the Department of Defense, are actively engaged in its use.

To access the government's electronic commerce system, a business would employ the services of a value-added network or VAN. VANs are private companies certified by the government that receive, share, sort, and list electronically all procurement opportunities routed through FACNET. Vendors can select from a variety of certified VANs to access procurement opportunities and exchange information. There are about 20 government-certified VANs operating at present.

Some small firms contend that the costs associated with using a VAN outweigh the relative benefits, at this time. VAN fees can range from \$50.00 to more than \$200.00 a month, depending on the company used and the services purchased. The costs of using a VAN prompted a White House Conference on Small Business recommendation that: "Small firms be provided free and easy access to the government's electronic commerce system, FACNET,

which profiles federal procurement opportunities."

Government procurement policy should require agencies to list all federal procurement opportunities in a uniform manner on the Internet. The technology is available now to do this -- this option should be pursued.

The Department of Defense (DoD) has committed itself to comprehensive use of EDI and EC. The DoD has applications of EDI and EC encompassing over 300,000 trading partners across several national and international industries. One-third of all of the federal government's existing or projected EDI/EC applications are DoD projects. For example, at several facilities, the DoD has been utilizing a Government Acquisition Through Electronic Commerce (GATEC) program, developed by Lawrence-Livermore Laboratories. GATEC automates Wright Patterson's Requests for Quotes (RFQ) on government contracts of \$100,000 or less.

The Department of Commerce is streamlining its acquisition functions through electronic commerce. DOC has conducted an extensive vendor outreach program to all small firms for the successful implementation of this electronic procurement network.

The National Aeronautic and Space Administration established a

Small Business Innovation Research (SBIR) program bulletin board
service as well as an Internet connection to assist small

businesses.

Reporting/Data Collection

On a yearly basis, the Internal Revenue Service (IRS) is probably the largest single information and data gathering organization in the United States. The IRS has proposed the adoption of procedures that would eliminate requirements that taxpayers keep paper records and allow, instead, an electronic imaging reporting system. The procedures would set forth certain requirements that imaging systems would have to meet to qualify as "books" as defined by the Internal Revenue Code. The requirements are broadly written as operational capabilities, not technical specifications for hardware or software. Taxpayers maintaining imaging systems in accordance with the procedures would not have to keep hard copy documents as a backup, thus saving taxpayer storage costs. This initiative, however efficient it may be, probably does not affect many small businesses.

In addition, the IRS, in conjunction with the Bureau of Labor Statistics and the Social Security Administration, is working on a massive project to convert all revenue-related reporting and filing information systems into electronic imaging.

A key element of the reform is the Simplified Tax and Wage

Reporting System (STAWRS) program. STAWRS is designed ultimately to reduce all small business revenue and employment reporting, to

federal and state governments, to a single quarterly, computerfiled report. Ideally, a small business owner would log onto a
computer in the office, call up the last quarterly report, make
the necessary changes in data or information and send it off to
all recipients. The recipients include the IRS, state revenue
authorities, the Social Security Administration, the Bureau of
Labor Statistics and the state unemployment compensation offices.

Unfortunately, there are a number of hurdles which must be surmounted to reach this worthy goal of simplified, unified electronic reporting. For example:

- a) In many cases, the laws and definitions of a state are different from those of the federal government or other states. This makes it difficult to get the same information on the same line of the same form unless all parties agree to changes;
- b) The initial cost to provide the federal government and the states with the technological capability to handle such a system and the training to become proficient is enormous;
- c) Current law prohibits the sharing of information first collected by the IRS without the permission of the taxpayer;
 - d) A large number of businesses, virtually all small, do not

have the equipment or the expertise to make the conversion to electronic reporting in the near future. Neither would they like to have to come up with the funds to hire a bookkeeping service to perform these functions for them.

Finally, while we support this effort, the Office of Advocacy has also suggested that simplified reporting -- meaning simple, unified, plain English tax forms -- be devised for small businesses with few than 10 employees, businesses that may not now have the computer literacy to file reports electronically and which may not likely acquire the capability in the near future.

The Environmental Protection Agency is a pioneer in the development of electronic reporting for federal reporting requirements. The premier EPA community "right-to-know" database, known as the Toxic Release Inventory database, has offered an electronic reporting option for several years. The Toxic Release Inventory (TRI) is a database which provides information to the public about releases of toxic chemicals from manufacturing facilities into the environment. The agency provides the manufacturer with computer software, allowing him or her the ability to fill out a computer generated report, and submit the required information on diskette. Besides simplifying the process of filling out the complex form, data from previous years can be transferred, saving time entering duplicative information from year to year. In addition, EPA strongly

encourages electronic submissions because it saves the agency millions of dollars in entering and verifying the data. Thus, benefits of electronic reporting flow to both the small business submitter and the government.

The agency is now in the process of establishing an electronic consolidation of all reporting requirements, which is now called one-stop reporting. There are four pilot projects in EPA's Common Sense Initiative to consolidate reporting for four different industries. For example, the Computer and Electronics CSI Subcommittee is developing the Combined Uniform Report for the Environment (CURE) reporting system. This system is designed to provide streamlined and consolidated reporting while providing electronic reporting and increased public access to the information.

Last March, the agency committed to developing "one-stop" reporting for the collection of all routine emissions data. In order to establish one-stop reporting, the agency is first implementing a Key Identifiers Initiative, which is intended to produce a single, authoritative set of facility information for public and governmental use. With a unique facility identifier, reporting for that facility with many separate and overlapping reporting requirements can be consolidated for "one-stop" electronic reporting for that facility. A Federal Register notice outlining the issues and options for the Initiative is

expected in the Spring of this year.

Finally, the EPA is going "live" with EDI for three of its reporting programs that total almost 50 percent of EPA's information-collection budget. Specifically, in June of this year, the Agency will begin to allow submitters to use EDI for the Discharge Monitoring Report, the Hazardous Waste Manifest, and Municipal Water System Laboratory reports.

The U.S. securities and Exchange Commission currently requires almost all corporate registration of stock issuances to be filed electronically. This is in order for the registrations to be listed on the SEC's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system. EDGAR is the Internet system which permits the SEC and investors to review stock offering registration filings by corporations. The only stock registration filing not on the EDGAR system is the filing under Regulation A. These are small business filings which are currently filed at the SEC's regional offices. Later this year Regulation A offering registrations will be filed at the SEC central office in Washington, DC. At this time, it is unknown as to whether Regulation A offerings will be added to the EDGAR system.

The federal banking regulators, the Federal Reserve Board, the

Office of the Comptroller of the Currency, the Federal Deposit
Insurance Corporation and the Office of Thrift Supervision,
currently permit small financial institutions to file
electronically.

The Customs Service initially became involved with EDI in the mid-1970's, piloting programs in several ports and the simple automation of customs forms. Later, Customs worked with the National Customs Brokers and Forwarders Association of America (NCBFAA) to implement a pilot program using brokers in Philadelphia and Baltimore which allowed brokers to submit import documents electronically throughout a system called Automated Broker Interface (ABI). The pilot was successful and ABI was implemented nationwide in April 1984. Today, the EDI system at Customs uses National Automated Clearinghouse Association's Automated Commercial System (ACS) which allows users to pay customs duties and other charges electronically, and a line release system to facilitate clearance of trucks entering the United States from Canada and Mexico, among other features.

The Paperwork Elimination Act of 1995, H. R. 2715

It is clear that technological innovations are gaining a toehold in the business of government, but many more agencies need to buy into the effort. It is also clear that the innovations can lead to significant cost savings by eliminating paper copies and the need for expensive file storage. To the extent that the current legislative proposal, H. R. 2715, clarifies Congressional intent behind the Paperwork Reduction Act of 1995, by requiring agencies to permit the "OPTIONAL" electronic filing of reports, the Office of Advocacy believes it can benefit small business — at least those with electronic capability. The key word in the legislation is "OPTIONAL". This allows firms to determine for themselves which is the least costly way for them to file reports. I leave to others the question of agency readiness to implement electronic filing.

It is also important that our efforts at regulatory reform, consistent with the recommendations of this year's White House Conference on Small Business, continue to emphasize simplicity of report content (not just process), reduced burden and elimination of duplicative reporting/data collection. The IRS' STAWRS effort, for example, could eliminate duplicative filing of the same basic information to several Federal and state agencies (Name of company, address, nature of business, number of employees, wages, deductions, etc.) by using the same form - a concept the Office of Advocacy has been promoting for two years. We recognize there are some obstacles to a simplified report form used for multiple purposes. But if a small business could save 2 hours a year by merely copying the same form to satisfy multiagency requests, that would represent a savings of 7,954,000 hours or 3,977 years of effort -- not insignificant. We continue

to hope that the IRS STAWRS effort will achieve such simplicity.

CONCLUSION

Most federal agencies are encouraging the use of the electronic medium for either information dissemination and/or data collection from business; and it is important that small firms fully utilize this technology to level the playing field between large and small firms and to allow them to participate in regional or global markets.

However, electronic filings have hurdles to overcome, as demonstrated by the experience IRS has had with its STAWRS program. Moreover, the medium needs to be adopted incrementally, and with the realization that some small firms may not ever seek to acquire such a capability. Accordingly, small firms must have alternative means available to them in fulfilling the data collection and information needs of the Federal Government. We need to be careful to avoid mandating any collections -- electronic or otherwise.

It is clear from the Paperwork Reduction Act that Congress and the President fully intended to make electronic filings available to the public for the submissions of data or information.

Agencies have been working toward reducing their own burdens, but our concern, as usual, is that small firms be protected from

additional burdens, and that <u>mandatory</u> electronic filings be avoided. By the same token, we are ever mindful that some federal agencies may delay offering electronic filings where it is both workable and cost-saving and may need an additional prod to provide the option.

I thank you for this opportunity to appear here today. I am happy to answer any questions the committee members may have.



U.S. SMALL BUSINESS ADMINISTRATION WASHINGTON, D.C. 20416



Testimony of

Monika Edwards Harrison Associate Administrator for Business Initiatives

U.S. Small Business Administration

Before

Subcommittee on Government Programs
of the
Committee on Small Business
U.S. House of Representatives

March 27, 1996

Good afternoon Mr. Chairman and Members of the Subcommittee.

I am Monika Edwards Harrison, Associate Administrator for

Business Initiatives at the U.S. Small Business Administration

(SBA). I want to thank you for inviting me to appear before you this afternoon to discuss SBA's Electronic Commerce/Electronic

Data Interchange (EC/EDI) training conferences.

Electronic commerce is the paperless exchange of business information using electronic data interchange, electronic mail, computer bulletin boards, fax, electronic funds transfer and other similar technologies. Electronic Data Interchange is the computer-to-computer exchange of business information using a public standard. It is a central part of electronic commerce because it enables businesses to exchange business information much faster, more accurately and at a lower cost than is possible using paper-based systems.

The SBA began its formal involvement in EC/EDI outreach and training activities in September 1993. At that time, SBA submitted to the Department of Defense EC Process Action Team a proposal to accomplish, for the Department of Defense, the education and training efforts necessary to help vendors move from a paper to paperless procurement system. That proposal became the basis for an Interagency Agreement between the Department of Defense and the SBA, signed in late September 1994

for activities to take place in FY 1995. The Interagency
Agreement with the Department of Defense represents a single part
of our comprehensive effort to inform, educate and train the
small business community on this important procurement reform
initiative.

All EC/EDI outreach activity has been geared toward three objectives: provide information to, educate, and train the small business community. The three objectives address distinct groups of small businesses interested in learning more about the government's transition to the use of EDI in procuring goods and services.

Clearly, existing government vendors needed to know that the conversion was taking place. A general information campaign to inform them of this transition was an important first step. Existing vendors also needed to be educated on the particulars of the government's implementation plan and trained in how to acquire an EDI capability.

A second audience, small businesses who have bid on government contracts but who have not yet become successful bidders, needed to be informed about the use of EDI and educated on the changes that the use of EDI might necessitate for their operations.

Finally, the broadest group, small businesses who have not yet bid on government contracts but may consider doing so in the future, needed to be informed about the impact of EDI on the government marketplace so that this component could be factored into their business decision if or when they chose to enter the government marketplace.

The principal activities conducted on behalf of the Department of Defense were "train-the-trainers" sessions for SBA personnel, SBA resource partner personnel and other Department of Defense affiliated organizations. The purpose of the train-thetrainers approach was to create a capability in institutions throughout the United States to inform, educate and train small businesses in their local areas. Between April 10-19, and on September 7, 1995, 542 representatives of organizations participated in train-the-trainers sessions. Of this total, 174 were SBA personnel, 266 were representatives from Small Business Development Centers, 27 were representatives from Women's Demonstration Sites, 52 were representatives from civilian Federal agencies, and 23 were representatives from Department of Defense affiliated organizations. Each participant was provided with a set of materials that could be used to conduct training in their local areas.

Following the train-the-trainers sessions, from May-September 30, 1995, a total of 172 training events, attended by 3,633 participants, and 1,650 separate counseling sessions were conducted across the country. During the first quarter of FY 1996, a total of 60 training events with 2,708 participants, and 704 separate counseling sessions were conducted. In total, we estimate that over 11,000 small businesses have been informed, educated, or trained under the auspices of the SBA/Department of Defense Interagency Agreement.

In addition to the activities conducted with and for the Department of Defense, the SBA has conducted a nationwide series of training seminars for small businesses. Under the SBA's cosponsorship authority, we have conducted 21 separate training events, with four additional events scheduled through April of this year. The events were announced in the "Commerce Business Daily," in "EDI World" and publicized widely in local media. A total of 3,188 small businesses have attended these cosponsored training events. We anticipate an additional 500 attendees will attend in the remaining four cities.

Entitled "EDI: Your Link to Profits," these half-day seminars provide an overview of the Federal government EC/EDI program. Step-by-step instructions show how to use EDI to conduct business electronically. These seminars are cosponsored by the APL Group, Inc., a software, professional services, and education group, and the National Contract Management Association. Client evaluations from these 21 seminars have

indicated a high level of satisfaction, with ratings averaging between 8.2-8.5 on a scale of 10.

To achieve our general information objective, we have created an electronic resource for accessing EC/EDI information on the SBA's electronic bulletin board, SBA Online, and on the SBA Home Page. Through these sources of electronic information, small businesses can learn about training seminars being offered by public and private sector organizations throughout the United States, gain access to a list of certified Value Added Network providers, discover which agencies are currently purchasing commodities through electronic data interchange, read answers to the 20 most frequently asked questions about EC/EDI and review a variety of Fact Sheets on EC/EDI-related topics.

Our electronic information is updated on a regular basis and new, more detailed topics are added frequently. SBA Online is accessed directly over 500,000 times per year; with an Internet access capability added late last year, the number may double.

To ensure that the information is accurate and current, the Associate Administrator for Business Initiatives convenes and chairs an Interagency Working Group of representatives from Federal agencies. These representatives provide official information on their activities to the SBA for inclusion in SBA Online. The group, convened four times in the last year, serves

as an informal source of information as well. As a result of our collaboration through the Working Group, SBA has been invited to participate in a number of panels at workshops sponsored by member agencies.

Lastly, as a part of our education objective, we have provided software that simulates EDI transactions between the government and vendors to all 27 of SBA's Business Information Centers (BICs). The software, developed by the APL Group for a government client, allows small business owners to understand, in a simulated environment, how EDI transactions are sent, received, responded to, acknowledged, and processed. This capability will enhance greatly our ability to educate those small businesses who are just beginning to consider the pros and cons of acquiring EDI capability. Also, each BIC has been provided with 200 copies of an SBA/Department of Defense handbook entitled "Your Introduction to Electronic Commerce."

Through a combination of information, education and training activities, the SBA has provided many thousands of businesses with basic information about EC/EDI and has increased awareness of the Federal government's implementation of a paperless procurement system.

Thank you, Mr. Chairman. That concludes my prepared remarks. I will be glad to answer any questions you may have.



ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF MANAGEMENT AND BUDGET WASHINGTON, D.C. 20503

STATEMENT OF SALLY KATZEN
ADMINISTRATOR
OFFICE OF INFORMATION AND REGULATORY AFFAIRS
OFFICE OF MANAGEMENT AND BUDGET .
BEFORE THE
SUBCOMMITTEE ON GOVERNMENT PROGRAMS

SUBCOMMITTEE ON GOVERNMENT PROGRAMS COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

March 27, 1996

Good afternoon, Mr. Chairman and Members of this Subcommittee. I am Sally Katzen, Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget. It is a pleasure to be here to discuss H.R. 2715, the "Paperwork Elimination Act of 1995." The thrust of this bill is to encourage agencies to use the electronic submission, maintenance, or disclosure of information to substitute for paper in order to reduce burdens on small businesses and other members of the public. This is a goal that we share. Where we differ, if at all, is the necessity -- or desirability -- of further legislation to achieve that goal.

To provide a context for my comments, I would like to step back a little and describe where we are regarding electronic transmission of information to the Federal government.

Background

Over the last decade, a number of important enabling technologies have been developed which are now reaching a stage of maturity that they can begin to be used in some large scale initiatives. The increasing availability of, and access to, data networks -- including the Internet -- coupled with the use of commercially accepted standards such as "Electronic Data Interchange" (EDI), and the increasing level of technology available to the public, are now coming together to make electronic filing and similar applications a reality.

These technologies are, however, neither magic nor free. Their use requires careful planning and development, often at significant expense, and they need to be tailored carefully to provide the benefits of burden reduction to the public without at the same time imposing unreasonable costs and technological burdens on those they are intended to assist or on the agencies. And, as necessary under the particular circumstances, these

systems must be designed to ensure an appropriate level of integrity and confidentiality of the information they contain.

Legal and Policy Framework

The articulation of legislative and administrative policy regarding the use of technology generally, and for addressing burden reduction specifically, has been an evolving process. The Paperwork Reduction Act of 1980 ('80 PRA) contained very little on agency use of information technology.¹ The 1986 amendments to the '80 PRA, as well as the first version of OMB Circular A-130,² discussed agency acquisition and management of information technology, but did not focus on using information technology to reduce paperwork burden.

This lack of focus was remedied with the 1993 revisions to OMB Circular A-130, which articulated a basic assumption that modern information technology can help the government and the public in the government's collection of information. While some information collections may not be good candidates for electronic techniques, many are.

The policy at Section 8a(3) of the Circular³ encourages agencies to use automated techniques for collection of information, and sets forth conditions conducive to the use of those techniques:

- "(3) Electronic Information Collection. Agencies shall use electronic collection techniques where such techniques reduce burden on the public, increase efficiency of government programs, reduce costs to the government and the public, and/or provide better service to the public. Conditions favorable to electronic collection include:
 - "(a) The information collection seeks a large volume of data and/or reaches a large proportion of the public;

For example, "automatic data processing and telecommunications technologies are [to be] acquired and used by the Federal Government in a manner which improves service delivery and program management ... and, where ever practicable and appropriate, reduces the information processing burden for the Federal Government and for persons who provide information to the Federal Government". 44 U.S.C. 3501(5), as enacted in P.L. 96-511 (December 11, 1980).

² 50 Fed. Reg. 52730, December 24, 1985.

³ 61 Fed. Reg. 6428, 6432 (February 20, 1996).

- "(b) The information collection recurs frequently;
- "(c) The structure, format, and/or definition of the information sought by the information collection does not change significantly over several years;
- "(d) The agency routinely converts the information collected to electronic format;
- "(e) A substantial number of the affected public are known to have ready access to the necessary information technology and to maintain the information in electronic form;
- "(f) Conversion to electronic reporting, if mandatory, will not impose substantial costs or other adverse effects on the public, especially State and local governments and small business entities."

It is significant, we believe, that this Circular emphasizes considering whether the respondent population has access to the necessary information technology, and directs agencies not to convert to electronic reporting if it would impose substantial costs on the public, especially small business entities. In the past, small businesses have complained about overly aggressive agency initiatives to automate reporting requirements. For example, the Social Security Administration (SSA) had been criticized for pushing small businesses too hard and too fast to file their wage and withholding reports on magnetic media. In response, SSA has been phasing in its electronic reporting requirements beginning with large businesses. It is now exploring a user-friendly modem dial-up technology to reach the remaining small businesses which have not yet been able to cost-effectively convert to electronic filing.

These policy concerns were codified in the Paperwork Reduction Act of 1995 ('95 PRA). A stated purpose of the '95 PRA is to "ensure that information technology is acquired, used, and managed to improve performance of agency missions, including the reduction of information collection burdens on the public." Agencies, in seeking public comment on proposed collections of information, are required to solicit public

⁴ P.L. 104-13, May 22, 1995.

⁵ 44 U.S.C. 3501(10). See also 44 U.S.C. 3504(h)(5), which calls upon agencies to "promote the use of information technology by the Federal Government to improve the productivity, efficiency, and effectiveness of Federal programs, including through dissemination of public information and the reduction of information collection burdens on the public."

comment to "minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology." Agencies, in submitting proposed collections of information for OMB review and approval, are also required to certify that the collection of information "uses information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public."

In signing the '95 PRA, President Clinton specifically recognized the concerns now reflected in H.R. 2715:

From this point forward, I want all of our agencies to provide for the electronic submission of every new government form or demonstrate to OMB why it cannot be done that way. The old way will still be available, but I think once people see how fast and efficient electronic filing can be, we'll see less paperwork and more of these. So, we're trying to do our part to act in good faith the way these Members of Congress intended the executive branch to act.

Last summer, OMB issued regulations implementing the '95 PRA. As part of those regulations, OMB explicitly included provisions directed at this Congressional and Presidential interest in having agencies expand the opportunities for the public to submit information electronically.

Before an agency sends OMB a proposed collection of information for our review, the agency is itself directed to review the collection. As part of its review, the agency is to conduct an "evaluation of whether (and if so, to what extent) the burden on respondents can be reduced by use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g, permitting electronic submission of responses." In connection with its review, the agency is to solicit comments from the public on a range of issues, including how the agency can "minimize the burden of the collection of information on those who are to respond, including through the use of automated,

^{6 44} U.S.C. 3506(c)(2)(A)(iv).

^{7 44} U.S.C. 3506(c)(3)(J).

Presidential Documents, May 29, 1995, Vol. 31, No. 21, p. 886.

^{9 5} C.F.R. 1320.8, 60 Fed. Reg. 44986 (August 29, 1995).

¹⁰ 5 C.F.R. 1320.8(a)(5), 60 Fed. Reg. 44989 (August 29, 1995).

electronic, mechanical, or other technological collection techniques or other forms of information technology."¹¹

After taking these comments into account, the agency is then to submit the proposed collection of information to OMB. For each approval, each agency is to certify that the proposed collection "to the maximum extent practical, uses appropriate information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public." 12

In addition to this certification, each agency is also to $\ensuremath{\operatorname{submit:}}$

a statement indicating whether (and if so, to what extent) the proposed collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g, permitting electronic submission of responses, and an explanation for the decision.¹³

Finally, the agency is to submit to OMB "a summary of the public comments received \dots , including actions taken by the agency in response to the comments \dots ."

Based on these materials from the agency, and the comments that the public submits to OMB directly, 15 OMB reviews proposed collections of information to confirm that agencies propose to maximize the use of information technology so as to reduce the paperwork burden on the public.

Finally, the recently enacted Information Technology Management Reform Act of 1996 (ITMRA), Division E of P.L. 104-106, is directly relevant to the electronic filing issue. ITMRA instructs agencies to reengineer their business processes before investing money to automate them:

[Agencies shall] analyze the missions of the executive

 $^{^{11}}$ 5 C.F.R. 1320.8(d)(1)(iv), 60 Fed Reg. 44990 (August 29, 1995).

¹² 5 C.F. R. 1320.9(j), 60 Fed. Reg. 44991 (August 29, 1995).

 $^{^{13}}$ 5 C.F.R. 1320.5(1)(1)(iii)(E), 60 Fed. Reg. 44987 (August 29, 1995).

^{14 5} C.F.R. 1320.5(a)(1)(iii)(F), 50 Fed. Reg. 44987 (August 29, 1995).

 $^{^{15}}$ 5 C.F.R. 1320.5(a)(1)(iv)(B)(6), 60 Fed. Reg. 44987 (August 29, 1995).

agency and, based on the analysis, revise the executive agency's mission-related processes and administrative processes, as appropriate, <u>before</u> making significant investments in information technology to be used in support of those missions. 16

The point here is that information technology should not be used simply to "automate the mess," but should be applied only after a concerted effort to consolidate and streamline agency processes has been completed. Part of the reason that agency electronic commerce initiatives have not yet been as successful as might have been hoped, is that agencies have too often been attempting to merely put electronic "front ends" on a paper-based procurement process.

Lastly, there are no significant legal issues regarding the admissibility of electronic documents as evidence in legal proceedings, and in certain circumstances electronic signature alternatives can be just as valid as traditional ink-on-paper signatures. **In the control of the control of

Agency Use of Technology to Reduce Paperwork Burdens

Over the last several years, we have started to see significant progress in agency implementation of these policies. Some examples follow:

1. U.S. Custom's "Automated Commercial System."

Eleven years ago, Customs began developing an automated system by which thousands of importers, many of them small businesses, would ultimately be able to transact all their business with Customs electronically. Today, over 96 percent of the paperwork associated with import transactions has been automated.

The benefits go far beyond paperwork burden reduction. This system now results in the rapid release of cargo into commerce, more predictable service from Customs, and large savings in the

P.L. 104-106, Sec. 5113(b)(2)(C) (emphasis added).

See, U.S. Department of Justice, "Admissibility of Electronically Filed Federal Records as Evidence" (October 1991), reprinted in "Information Resources Management Plan of the U.S. Government," (December 1991); Perritt, "The Electronic Agency and the Traditional Paradigms of Administrative Law," 44 Administrative Law Review 79 (Winter 1992); and Weiss, "Security Requirements an Evidentiary Issues in the Interchange of Electronic Documents," XII:3 John Marshall Journal of Computer & Information Law 425 (October 1993).

cost of doing business. A major ocean carrier recently reported that by submitting ship manifests electronically, its paper costs alone were being reduced by over one million dollars per year. A major importer reduced its interest expenses by over two million dollars a year through a combination of early submission of data electronically and Customs processing that data in advance of the goods arriving in the United States.

More recently, Customs offered the importer community the option of electronic payment of duties, taxes and fees. The importers embraced it. Customs is now collecting over fifty million dollars per day electronically. This means that the importers do not have to cut checks, reconcile them, or do all of the manual work associated with checks. It also means that the government receives its money faster and more securely. Customs now processes fewer than half the number of checks that it did just two years ago.

In light of these successful experiences, Customs is working on other promising applications. It is now receiving passenger manifests from air and sea passenger carriers electronically. This is beginning to improve the speed by which Customs can process the travelers. Customs is also working in partnership with other government agencies to define and create a single, comprehensive government-wide international trade data system. The system will replace much of the redundant data collection and processing currently performed by multiple agencies such as Customs, the Agriculture Department, and the Food and Drug Administration, and replace it with a single point of entry for all import and export data -- simplifying the way in which businesses and the public interact with the Federal government.

2. Securities and Exchange Commission's "EDGAR" System.

The SEC's electronic filing system, known by the acronym EDGAR (which stands for Electronic Data Gathering Analysis and Retrieval), is just now realizing the promise envisioned for such systems by the Paperwork Reduction Act. As of May 6 of this year, 10,000 domestic, publicly traded corporations and over 12,000 mutual funds registered with the SEC will be filing almost everything they submit to the SEC electronically.

This translates into something between 10 and 12 million pages of information annually that no longer have to be submitted in multiple copies (sometimes numbering as many as 13), sent by courier to the SEC, manually distributed to staff and public reference rooms, stored, tracked, microfiched and archived in difficult-to-handle media.

Businesses are now able to transmit an average 42 page document to the SEC from anywhere in the country in about 35 seconds using a very basic PC and a modem. They receive a

response as to whether the filing was accepted or not within minutes via electronic mail and never have to worry about catching the last flight out of town or whether National Airport will remain open during an approaching storm.

Companies and mutual funds began to phase-in their use of this system in April of 1993, and it has proceeded smoothly. The system has also proven itself to be easy for filers to use. 96 percent of all filings entering the system are successfully filed and accepted on the very first try.

3. Internal Revenue Service's "TeleFile" system

As of March 15, 1996, nearly 2.4 million Form 1040EZ filers had already taken advantage of a new nationwide system which allows them to file using touch-tone telephones. TeleFile is an interactive voice system similar to those used to administer bank accounts, check on stock transactions, and even to register for unemployment benefits in some states.

Through a 1995 customer survey approved by OMB under the PRA, 99 percent of those using Telefile were very satisfied or somewhat satisfied with the experience. Based on 1994 and 1995 surveys, 95 percent of those who used Telefile stated that they would plan to use it again, if they are still eligible. Over 85 percent of those who used Telefile in 1995 were able to complete their filing with a single telephone call.

IRS is attempting to calculate the burden reduction attributable to Telefile. There clearly are burden reductions associated with preparing to file, putting pen to paper, and recordkeeping. The number of burden hours saved may well be in the millions. In addition, this free service results in refunds being sent to taxpayers in about three weeks -- half the time as refunds based on paper filing.

In addition to TeleFile, IRS electronic burden reduction initiatives include the Electronic Filing system (ELF) which has already processed over 9.8 million Form 1040's so far this year, and the issuance of a proposed Revenue Procedure to allow large and small business taxpayers to use digital imaging technology to store their business records electronically and actually destroy the paper documentation. Since administration of the tax laws is the country's greatest source of paperwork burden, IRS electronic filing initiatives can have particularly beneficial impacts.

4. Environmental Protection Agency's Electronic Reporting Project.

EPA's strategy to reduce industry burden and streamline regulatory programs by using appropriate data transfer technologies is to begin with high volume and large burden EPA

reports and to work initially with the larger companies which submit the lion's share of data under most EPA programs.

EPA's approach is to take advantage of existing "Electronic Data Interchange" (EDI) standards already in use among most large companies. As EPA gains experience, it intends to develop initiatives for small business submitters, including working with private sector software developers to foster a market for automation tools analogous to the popular tax preparation software packages now widely available.

EPA has set three goals for Fiscal Year 1996 in this area:

- To "go live" with pilot EDI applications for the three reporting programs which account for nearly half of EPA's information collection budget. EPA will begin allowing submitters to use paperless EDI for the discharge monitoring report (DMR/NPDES), the hazardous waste manifest, and municipal water system laboratory reports.
- To publish a general EPA policy on the implementation of EDI. This will establish EPA's approach to authentication and security issues and set forth the general terms and conditions under which EPA will accept electronic submissions.
- o To demonstrate "business process reengineering" methods by streamlining a specific industry's compliance with related Federal, state and local environmental regulations. This pilot will be aimed initially at assisting small metal finishing companies.

5. Department of Veterans Affairs' "Electronic Commerce" Programs.

The Department of Veterans Affairs (VA) is an example of an agency which has worked to identify those aspects of the procurement process which are most readily automated and to apply industry EDI standards to the automation process.

In 1987, the VA began to pursue the use of industry standards by first automating its invoice process. Today it electronically receives approximately 350,000 invoices from its vendor community. It is also now making approximately 1.2 million electronic funds transfer payments annually.

Automating the invoicing and payment process, however, is only a first step. In 1993, the VA completed designing a more comprehensive electronic commerce program, including issuing EDI purchase orders to vendors and receiving order acknowledgments from them. VA now processes approximately 70,000 purchase orders and 100,000 vendor acknowledgments. With this implementation,

the VA completed its initial goal of reengineering its business process from issuing an electronic purchase order to making the resulting payment electronically. So far, the VA has automated its commercial relationships with 153 vendors, of which fully 85 percent are small businesses.

The VA's future efforts will be to make greater use of the newly available government bank cards to eliminate nearly all of the paperwork associated with the smaller purchases which are not yet automated, and to pilot a competitive small purchase "Request for Quotation" process at twenty VA facilities.

6. Census Bureau Use of Electronic Data Reporting.

The Census Bureau is making use of a variety of electronic data collection techniques in its surveys and censuses. These new technologies will help the Bureau reduce response burden, increase the timeliness of data collection, eliminate laborintensive activities such as data entry and processing, improve the quality of the data collected, and reduce data collection costs. Although a few applications have had problems associated with them, none have been considered to be unsuccessful.

- o The Bureau's <u>Foreign Trade Statistical Program</u> has been highly successful in its use of electronic reporting. Over ninety percent of the import data are reporting on computerized forms and about fifty percent of the export data are reported electronically.
- The Bureau also uses the Computerized Self-Administered Questionnaire (CSAQ) to reduce respondent burden. A Computerized Self-Administered Questionnaire is delivered to respondents either by mailing floppy disks loaded with the CSAQ or transmitting the CSAQ by modem. The CSAQ leads the respondents through the questionnaire and allows them to respond interactively. This technology is being used in several surveys including: the Company Organization Survey; the Annual Survey of Manufactures; and the Survey of Industrial Research and Development. The Bureau has found this to be very successful, and has made use of contractors to develop the software efficiently and quickly.

As demonstrated by these examples, successful agency electronic filing initiatives share the following characteristics:

- Identifying an application where the technology is readily and cost-effectively available;
- o Reengineering the business process before attempting to automate that process;

- Planning the transition to electronic filing in steps which will not place undue burdens on respondents, particularly small businesses;
- Building in appropriate and cost-effective security and integrity controls; and
- Constantly improving the efficiency of the system in close coordination with users.

H.R. 2715

H.R. 2715 would amend the Paperwork Reduction Act of 1995 to make more explicit that agencies should use alternative information technologies for the maintenance, submission, or disclosure of information. While the objectives of this bill are laudable, we have concerns about both the timing and the content of the proposed legislation. We are admittedly looking at this bill with some skepticism because over the past few years it has become increasingly clear that not every problem is best solved by legislation, nor is every aspiration best achieved through a new statute.

As we read this bill, it makes very clear Congress's expectation that agencies are to do everything they can to provide opportunities for, and indeed promote the use of, electronic maintenance, submission, or disclosure of information. If this reading is correct, we question the timing of this legislative effort. The Paperwork Reduction Act of 1995, which is the vehicle for this legislation, only took effect on October 1, 1995, and ITMRA will only take effect on August 8, 1996. Moreover, OMB is in the middle of developing amendments to OMB Circular A-130 (which was itself only recently revised) to reflect the new legislative responsibilities assigned by ITMRA.

In addition, it is possible to construe one provision in H.R. 2715 as requiring that all agencies accept electronic submissions. 18 We believe that such a mandate would be a

The proposed amendments in Sections 3(b), 5(b), 5(c), and 6 of H.R. 2715 expressly recognize that it is not always "appropriate" or "practicable" for an agency to provide for optional electronic maintenance, submission, and disclosure of information. However, the amendment in Section 5(a) might be read to impose a blanket duty on agencies to offer the option of electronic maintenance, submission, or disclosure in all cases. Section 5(a) would amend Section 3506(c)(1)(B) of the '95 PRA to read that "each agency shall (1) establish a process ... to ... (B) ensure that each information collection ... (iv) provides for the optional use of electronic maintenance, submission, or disclosure of information." We would recommend, consistent with existing

mistake. In its other provisions, the bill correctly recognizes that not all small businesses have the technical or financial capacity to make use of information technology and therefore that such a requirement should be optional. So too should Congress recognize that not all agencies have the capacity to use information technology at this time. To insist on this now would, we believe, result in agencies making significant investments in information technology before they have finished reengineering their work processes. Yet, to be most effective, there needs to be careful planning, proper implementation, and due concern for the capabilities, technical abilities, and financial resources available to the public respondents and the agencies. Indeed, the ITMRA explicitly warns against merely "automating the mess."

* * * * *

My examples of agency progress, and praise for these efforts, are not intended to give all the agencies an A for effort. Many agencies are just beginning; and there is much more to be done. We welcome your interest in encouraging agencies to move forward. We would like to discuss with you ways in which we can use your support to encourage agencies to increase their use of information technology in a sensible, workmanlike way. Hearings such as this and ongoing Committee oversight can certainly help us in our efforts to reduce paperwork burdens on the public.

Thank you for the opportunity to appear today before you. I am happy to answer any questions you may have.

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legislation and the President's signing statement, that Section 5(a) be amended, consistent with Section 5(b), by inserting "where appropriate," after the verb "provides,".



Public Health Service

Food and Drug Administration Rockville MD 20857

STATEMENT FOR THE RECORD

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON GOVERNMENT PROGRAMS

COMMITTEE ON SMALL BUSINESS

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 27, 1996

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Subcommittee:

The Food and Drug Administration (FDA) appreciates the opportunity to submit this statement for the record. In keeping with the theme you set for the hearing, this statement will focus on FDA's efforts providing for the electronic submission and dissemination of data and our comments on your legislative proposal, H.R. 2715, the Paperwork Elimination Act of 1995.

As you know, FDA's primary statutory mandates are in the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and the Fair Packaging and Labeling Act. Our mission under these statutes is to protect, promote and enhance the public health by implementing statutory provisions designed to ensure that food is safe and otherwise not adulterated or misbranded; that human and veterinary drugs, human biological products and medical devices are safe and effective; that cosmetics are safe; and that electronic product radiation is properly controlled. FDA-regulated products must be truthfully and accurately labeled and in compliance with all applicable laws and regulations.

While FDA principally serves the general public in its health and safety mission, FDA also recognizes it has responsibilities to the industries that it regulates. Industry demands speedier product approvals to help offset the large sums of research dollars expended to develop new products. The public demands timely access to medical innovations, especially life-saving innovations, but without sacrificing health and safety. FDA sees its mission as meeting both these goals simultaneously. We are using new information technology to better serve the regulated

industry which develops the innovative products we are charged with reviewing and the consuming public which rightfully expects timely access to new or improved products but with the same assurances of their safety and effectiveness as they have come to expect from the FDA.

Congress recognized the need for FDA to adopt modern technologies in 1987 when it added Section 711 to the Food, Drug, and Cosmetic Act directing FDA to "automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this Act." In 1993, Vice President Gore's National Performance Review (NPR) recognized the power of information technology to reinvent government and reengineer agency practices to increase the speed and efficiency of government functions. The NPR set an objective of expanded use of new technologies and telecommunications to create an "electronic government." And last May, when he signed the Paperwork Reduction Act of 1995 (PRA), President Clinton reemphasized his commitment to reducing the paperwork burden through the use of new technology when he said:

Today, I want to add another dimension to this effort: From this point forward, I want all of our agencies to provide for the electronic submission of every new Government form or demonstrate to OMB why it cannot be done that way. The old way will still be available, but I think once people see how fast and efficient electronic filing can be, we'll see less paperwork and more of these. So, we're trying to do our part to act

in good faith the way these Members of Congress intended the executive branch to act.

STRATEGIC APPROACH

FDA is using a strategic approach to address the challenges of implementing information technology for the 21st Century. To keep our information systems as flexible and up-to-date as possible, FDA tries to keep its computer systems environment one that is open to evolving technologies. We have an Information Systems Architecture initiative which concentrates on the development of a common information technology infrastructure throughout the Agency. Our objective is to take full advantage of the evolving capabilities offered by information technologies and electronic communication to facilitate information exchange between the FDA, industry, and the public. More readily accessible information; easy-to-use systems interfaces; and fully integrated databases, information systems, and analytical tools will combine to enhance the productivity of FDA personnel and facilitate the exchange of information with industry and the public, for both programmatic and administrative purposes.

While many of the factors that influence FDA's environment will change over the next decade, one thing will not change: the Agency is and will continue to be an information-intensive organization. FDA must collect, analyze, and maintain

significant amounts of data collected from pre-market approval and post-market surveillance of regulated products.

Our systems serve both big and small business -- we try to make any system we develop accessible to both. It is FDA's objective to provide the most efficient information systems we can to lighten the reporting burden on business as well as consumers.

HIGHLIGHTS OF RECENT ACTIVITY

FDA's information activities often serve multiple communities simultaneously. However to provide some order in presenting our activities, we will categorize some of our recent activities by the primary client group affected: consumers and users of regulated products, industry generally, and small business specifically.

SYSTEMS SERVING CONSUMERS OR PROVIDERS OF FDA REGULATED PRODUCTS

INTERNET HOME PAGE. The FDA Home Page is an agency initiative, designed to improve the efficiency and effective dissemination of information via the Internet. For example, guidance documents to assist in development of food additive petitions are available through the home page, as is information on food, cosmetics, human and animal drugs, biologics, medical devices and radiological health products. In addition, FDA is beginning to receive information from

both industry and the general public via Internet, and is exploring ways to institutionalize and optimize use of this technology.

ADVERSE EVENTS REPORTING. The MEDWATCH program, an upgrade and enhancement of earlier systems, was introduced in June 1993 to enhance the effectiveness of postmarketing surveillance of all medical products regulated by the FDA, e.g., drugs and biologics as well as medical devices and special nutritional products such as medical foods, dietary supplements, and infant formulas. The program has four general goals: 1) to increase awareness of drug- and deviceinduced disease, 2) to clarify what should (and should not) be reported to the agency, 3) to make it easier to report, and 4) to provide regular feedback to the health care community about safety issues involving medical products. The MEDWATCH program is supported by more than 100 organizations - representing health professionals and industry - which have signed on as MEDWATCH partners to help achieve these goals.

To facilitate reporting, there is a one-page, postage-paid, voluntary form for health professionals who choose to report directly to the agency and/or the manufacturer. A 24-hour toll-free number (1-800-FDA-1088) is also available for health professionals to report by phone, to request forms either via fax or mail, or to obtain a copy of the FDA Desk Guide to Adverse Event and Product Problem Reporting, which includes examples of events to report, completed sample

forms, and also blank forms with instructions. Providers may also report to the FDA electronically (on-line) by calling 1-800-FDA-7737, or fax a report on 1-800-FDA-0178. Currently the majority of adverse events reports are received via the manufacturers in computer print-out form that have to be re-entered into FDA's data system. The Adverse Events Reporting System (AERS) is an effort to strengthen the database systems and processes of our postmarket surveillance programs. To support the database, we will encourage and facilitate electronic reporting of adverse events by industry and health care providers. The AERS initiative will provide a database of adverse events information and enhanced evaluation capabilities.

SYSTEMS SERVING INDUSTRY GENERALLY

VIDEO TELECONFERENCING. Video teleconferencing enhances communications with regulated industry, especially between the product sponsor and the FDA reviewers during the review process. Several small manufacturers have taken advantage of this new technology which allows both parties to see and hear each other during the session in addition to allowing them to modify a submission interactively. This system also provides a medium for training Agency and industry personnel.

FORMS AVAILABILITY. FDA is participating in efforts of our parent Department of Health and Human Services, currently in

the conceptual stage, to make forms accessible via the Internet. This system will give industry direct access to a library of forms they currently must solicit either verbally or in writing.

NEW DRUG AND BIOLOGIC APPLICATIONS. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have for years been exploring electronic submissions of portions of new drug applications, including data sets and data summaries. CDER has received over a hundred electronic submissions. With the passage of the Prescription Drug User Fee Act of 1992 (PDUFA) Congress established specific goals for reducing the time it takes to review new drug and biologic product applications. Despite the progress made with electronic submissions, the current process for reviewing applications is time-consuming and paper intensive. With money obtained from user fees, the agency has begun the Submission Management and Review Tracking (SMART) Program. SMART currently supports CBER and CDER through several pilot projects. The program will facilitate submission of product applications electronically, and will improve the Agency's ability to process, track, and archive submission data. SMART will provide automated tools to help managers in making informed decisions, determine the status of applications, and assess the efficiency of the review process, and to assist reviewers in accessing, analyzing, sharing, and producing relevant information.

Import Support (OASIS) is an automated system designed to facilitate inspection and clearance of imported products regulated by FDA. The amount of paper import brokers provide to FDA as part of the entry process was reduced by 85% through application of information systems technology. A 1995 cost/benefit study by Booz-Allen and Hamilton shows that the import industry will save more than \$1.2 billion over the period from 1994 through 2001 because of paperwork reduction and expediting of the entry process.

In February 1996, 80 percent of all shipments of FDAregulated products processed in the electronic system
received a final clearance within minutes after the
electronic data was submitted. These short clearance times
are a great improvement over the one, two or more days that
it took to clear products before automation. This system
also allows FDA to focus its scarce resources on those
import shipments that are suspected of not meeting
regulatory requirements.

BLECTRONIC MEDICAL DEVICE APPLICATIONS. Based on results of a pilot study begun in 1994, the Center for Devices and Radiological Health (CDRH) has started accepting medical device applications in electronic form for Premarket Notifications (so-called 510k's), Premarket Approval (PMA) Applications, and Investigational Device Exemptions (IDE). The applications were developed specifically with the small manufacturer in mind. They do not require expensive, sophisticated equipment. Already a dozen such applications

ELECTRONIC RECORDS AND SIGNATURES. In the Federal Register of August 31, 1994, FDA proposed regulations that would define the circumstances which would permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations would apply to all records required under FDA regulations (Chapter I, Title 21 of the Code of Federal Regulations). Under the proposed rule, firms could choose to use electronic forms of recordkeeping for records they are required to maintain. Firms could also submit data to the agency electronically when the agency has announced its ability to accept such electronic submissions.

The intended effect of this proposed rule is to promote the optional use of electronic maintenance and submission of information, reduce paperwork burdens, improve data reliability, and enhance agency efficiency and responsiveness in a manner that is compatible with FDA's ability to promote, protect and enhance the public health. This is a significant rule that we are working hard to finalize.

SYSTEMS OF PARTICULAR BENEFIT TO SMALL BUSINESS

IMPORT SURVEILLANCE. Import brokers are mainly small businesses. Operational and Administrative System for have been processed. One medical device manufacturer has estimated a 20% savings in document submittal time resulting from this approach.

SMALL PURCHASES. Our Office of Facilities, Acquisitions, and Central Services has initiated a pilot project using electronic data interchange (EDI) for product acquisition, soliciting small businesses, receiving quotations and awarding purchase orders electronically for a small number of requirements.

on-DEMAND and FLASH FAX, are being used in various programs throughout the agency to expedite information exchange with consumers, health professionals, and the industry. Each of the Agency's thirteen 800 numbers has a target constituency and purpose. Examples include: the Seafood Safety Hotline, MEDWATCH mentioned earlier, the Advisory Committee Hotline, the Orphan Product Development Information Line, and lines providing assistance in the areas of drugs, medical devices, biologics and general consumer information. Using these technologies to disseminate information to over a half million callers each year has significantly reduced the paperwork burden on the Agency.

CASE STUDY OF RAPID TECHNOLOGICAL CHANGE.

What follows is a short case study of how the agency is changing and adapting its services to industry to keep pace with the rapid change of technology. This chronicles efforts of the Division of Small Manufacturers Assistance in FDA's Center for Devices and Radiological Health (CDRH), to assure that any use of new technologies is of advantage to the small device manufacturer.

ELECTRONIC DOCKET. In 1994 CDRH established an Electronic Docket which includes publicly available documents such as guidance memoranda, talk papers, and press releases. A comparison of accesses to the Electronic Docket with the Public (paper) Docket found the Electronic Docket to be considerably more popular, with thousands of accesses a month on the Electronic Docket, compared to tens of accesses to the public docket. These findings resulted in discontinuation of the paper docket. The major advantage of the electronic docket was the addition of 510k application status listings. Small manufacturers no longer had to telephone a reviewer to find out the status of their Premarket Notification (510k) but could find out via simple access from a personal computer.

CDRH INTERNET HOME PAGE. With the introduction of the Internet CDRH decided to convert the Electronic Docket to make that same information available on CDRH's Home Page on the World Wide Web. The advantage to the small manufacturer is that more information is available in a more easily

require that low acid canned foods be physically marked with a can code. This is critical in the event of a manufacturing or handling failure that requires the identification of potentially hazardous product.

If we may paraphrase, the stated purpose of H.R. 2715 is to promote the sponsorship and use of alternative information technologies to: (1) minimize the burden of federal paperwork demands on small businesses, and (2) more effectively enable Federal Agencies to achieve the purpose of the Paperwork Reduction Act. As you saw from the list of highlights above, FDA has been working for many years to incorporate alternative information technologies in our system. As you know, these types of changes do not happen quickly. They take planning and money. For a number of years, the agency has been investing some of our scarce resources in this large effort to take firmer control of the many demands being made on us. It is not clear what additional impetus the provisions of H.R. 2715 would provide. are already moving in the direction envisioned by H.R. 2715 propelled by the needs of our clients for more information provided as quickly as possible, the budgetary constraints of our times demanding that we seek more efficient means of fulfilling our mission, and encouraged by Section 711 of the FDC Act, the National Performance Review and most recently by the President's own statement.

Thank you again for giving us the opportunity to present our views on this important topic.

searchable manner. Statistics show that this mechanism is now taking precedence over the Electronic Docket, which may be phased out in the near future.

In summary, as demonstrated by the listing of alternative technologies and the case study, while many of the factors that influence FDA's environment will change over the next decade, one thing will not change: the Agency is and will continue to be an information-intensive organization. FDA must collect, analyze, and maintain significant amounts of data from pre-market approval and post-market surveillance of regulated products. The judicious implementation of alternative technologies will be an absolute necessity for the agency to gain the efficiencies needed to enhance our services to the public and the regulated industry within the budget constraints of the foreseeable future.

COMMENTS ON H.R 2715

We have one technical comment. In Section 5(a) of the proposed legislation, the words "when appropriate" should be inserted before the semicolon. This change is consistent with the wording of the other sections of the proposed legislation and is necessary because, in some cases, electronic maintenance, submission, or disclosure of information would not serve the purposes of the Food, Drug, and Cosmetic Act and its regulations; for example, it is important that FDA be able to continue to

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